# CAPACITY BUILDING TOWARDS ACCREDITED CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS IN ETHIOPIA

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## DECLARATION

The author hereby declares that the work contained in this thesis is her own original work and that she has not previously, in its entirety or in part, submitted it at any other university for a degree.

| Anya Knoetze |  | 25 September 2019 |
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| **Name** | **Signature** | **Date** |

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## ABSTRACT

Food has become an easy commodity to trade, especially on continents where many countries are stricken by poverty, drought, food insecurity, political uncertainties and various types and forms of disease and health challenges based on, for example, malnutrition. Food can be produced by small businesses and trade can be informal in order to sustain a community. The export of food is, however, required to support economic growth, and cross-border trade has become increasingly formal through the demands in the trading of safe food. The burden of food-borne disease, its link to food insecurity and possible litigation for the food handler has led to the development of controlled food safety management systems (FSMS). Some systems are voluntary through the application of national or international standards and some systems are being used to ensure trade through the application of private standards and schemes, which in some way appears to be mandatory in order to trade, but is still not regulatory. Both system types are in demand to demonstrate verified compliance with the overall aim to mitigate food safety risks. The need to comply with such systems is a burden to the food handler and, as such, is a constraint to sustainable economic development. They are perceived by some to be an additional technical barrier to trade.

In developing countries, the informal food trade as a means of sustainable livelihood has been increasing and is thus becoming a potentially valuable resource for trade with developed countries. Through their membership of the WTO, which has an obligation to support developing nations, such countries are provided with various types of sponsored assistance intended to help them achieve necessary economic growth and sustainability. The trading agreements of the WTO support developing countries with the eradication of barriers to trade, but also place them in a position to participate in verified compliance with international standards and best practices. This has led to food handlers of developing countries being faced with the dilemma of only being able to engage in cross-border trade when formal food safety certification can be demonstrated.

Ethiopia, is similar to many of the developing countries on the African continent in terms of its challenges to be sustainable and to grow economically. As such, it became one of the nominated sponsor countries that had to be supported with the development of their National Quality Infrastructure (NQI). Some parts of the NQI had already been established, but required assistance to ensure their proper functioning, especially towards food safety control and certification needs in terms of conformity assessment. Various donor organizations have frequently been deployed to Ethiopia and are working collectively on building capacity in support of sustainable development and economic growth. One of the sponsor programmes involved in the support to the Quality and Standards Authority of Ethiopia (QSAE) was the Ethiopian Conformity Assessment Enterprise (ECAE). The ECAE had to set up an FSMS certification scheme for Ethiopia with the overall aim to be accredited as part of the functional operation of the NQI within the country.

This study was conducted in Ethiopia in support of building capacity towards the establishment, application and accreditation of an FSMS certification scheme based on ISO 22000 (2005). The project stemmed from efforts applied to developing countries as part of the WTO's role and responsibility in promoting trade, supporting developing countries and ensuring the appropriateness of NQIs in accessing global markets. The aim of the study was primarily to establish the success of this mediation and the application of experts through a donor funding organization. The study ultimately aimed to assess the effectiveness of capacity building projects instituted by donor organizations on the establishment, for example of sustainable FSMS certification through NQI development, utilizing Ethiopia as a case study.

An overview analysis was conducted to establish the collaborative roles of the NQI role players in relation to the needs for the operation of a certification body and in general the support to a food handler who requires certification and also to ensure safe food is produced, handled and traded.

The emphasis of the study was placed on the activities, processes and competencies of the ECAE, the nominated 'national' certification body in Ethiopia. The ECAE was already certifying against the ISO 9001 standard, applied for quality management systems (QMS), and had already achieved the accreditation for this certification scheme. These certification processes had to be extended to include

food safety, and in particular ISO 22000, a recognized international standard applied to support the trade of safe food.

Further empirical work included a gap assessment of the QMS manual established for QMS certification and all the relevant certification processes that could be applied to food safety certification and also in what way food safety certification processes can be integrated with the QMS certification processes. The assessment of the QMS manual was consequently extended to the auditor pool to determine whether the current pool of auditors qualified for the competency requirements set out by the international standard for food safety certification, for example ISO/TS 22003 (2007).

The study subsequently investigated, and developed training sessions for food safety certification personnel. This involved lecture-based training on the developed FSMS certification processes as well as overviews of the ISO 22000 standard and its application in a food handling facility. The classroom training was supported by the practical application of food safety auditing practices in the field where certified and non-certified food facilities were visited.

The study was conducted over a period of two years and encompassed assessments, identification of gaps, development of the required certification processes, and progress assessments with regard to the application of the developed processes to ensure a successful accreditation of the FSMS certification scheme.

Information available on NQI on high-level was found to be readily available, however operational food safety-specific information relevant to Ethiopia was limited. Literature highlighted the fact that developing countries, which include Ethiopia, face challenges with the development and on-going effective and viable application of a NQI framework due to, for example lack of resources. Technical barrier to trade are a further predicament that developing countries have to contend with. It is suggested that a carefully planned assessment of the level of capacity and therefore the level of the need for capacity building be carried out and evaluated before a capacity building project is initiated. Through the gap analysis conducted this study further found that the primary QMS provided by Ethiopian Certification Directorate was generally falling short of supporting further incorporation of a secondary certification scheme. In

chapter 4 of this study an assessment was done to measure implementation of gap analysis related strategies following an agreed period. The result showed that the strategies suggested during phase 1 were not implemented due to various reasons, with the result that the next phase of capacity development could not be realised.

The study findings ultimately suggest that donor-based capacity building projects do not always have the intended result, primarily due to poor project management, resistance to change and unrealistic time frames. Also, the beneficiaries did not take adequate ownership of the initiatives. The study further revealed that unique dynamics related to national characteristics such as culture, change management resistance, race and gender considerations, traditional beliefs, etc. play a fundamental role in the success of implementation of FSMSs by external (international) experts. It is recommended that national and culture dynamics be a consideration in selecting beneficiaries, international experts, methodologies and strategies, and be reflected in the development of novel project management approaches.

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| | |
|---|---|
| **BIPM** | Bureau International des Poids et Mesures<br>(International Bureau of Weights and Measures) |
| **BRC** | British Retail Consortium |
| **CB** | Certification Body |
| **CODEX** | Codex Alimentarius Commission |
| **DCMAS** | Developing Countries in Metrology, Accreditation and Standardization |
| **DFID** | Department for International Development<br>(a United Kingdom government department) |
| **ECAE** | Ethiopian Conformity Assessment Enterprise |
| **ECAE Cert** | Ethiopian Conformity Assessment Enterprise Certification |
| **ES** | Ethiopian Standard |
| **FAO** | Food and Agricultural Organization of the United Nations |
| **FSMS** | Food Safety Management System (based on ISO 22000) |
| **FSSC 22000** | Food Safety System Certification 22000 |
| **GAP** | Good Agricultural Practices |
| **GATT** | General Agreement on Tariffs and Trade |
| **GIZ** | Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH<br>(German Development Agency) |
| **HACCP** | Hazard Analysis and Critical Control Point |
| **IAF** | International Accreditation Forum |
| **IEC** | International Electrotechnical Commission |
| **ILAC** | International Laboratory Accreditation Cooperation |
| **IRCA** | International Register of Certified Auditors |
| **ISO** | International Organization for Standardization |
| **ITC** | International Trade Centre |
| **NAB** | National Accreditation Body |
| **NFCS** | National Food Control System |

| | |
|---|---|
| **NMB** | National Metrology Body |
| **NQI** | National Quality Infrastructure |
| **NSB** | National Standards Body |
| **PRP** | Prerequisite Programme |
| **QMS** | Quality Management System (based on ISO 9001) |
| **QSAE** | Quality and Standards Authority of Ethiopia |
| **SANS** | South African National Standard |
| **SI** | Système International |
| **SPS** | Sanitary and Phytosanitary |
| **TBT** | Technical Barriers to Trade |
| **ToR** | Terms of Reference |
| **UK** | United Kingdom |
| **UNDP** | United Nations Development Programme |
| **UNEP** | United Nations Environment Programme |
| **UNESCO** | United Nations Educational, Scientific and Cultural Organization |
| **UNIDO** | United Nations Industrial Development Organization |
| **WHO** | World Health Organization |
| **WTO** | World Trade Organization |

# CHAPTER 1

# INTRODUCTION

## 1.1 Food quality, food safety and their management systems: Defining the concepts

The term ‘quality’, according to ISO 9000 (2005), is defined as the ‘degree to which a set of inherent characteristics fulfils requirements’. ISO 9000 goes further in explaining that ‘inherent’ means ‘existing in something, especially as a permanent characteristic’, whereas ‘characteristic’ means a ‘distinguishing feature’. Classes of characteristics are explained as ‘something physical, sensory, behavioural, temporal, ergonomic and functional’ leading us therefore to a ‘requirement’, explained by ISO 9000 as ‘the need or expectation that is stated, generally implied or obligatory’. ‘Generally implied’ on the other hand means ‘that it is custom or common practice for the organization, its customers and other interested parties, that the need or expectation under consideration is implied’ (ISO 9000, 2005).

Food quality can then be determined to be the characteristics of food that makes it acceptable to consumers. Factors such as size, shape, colour, gloss, consistency, texture, flavour, and grade are characteristics of food influenced by the consumer and form part of the physical properties of food that can objectively be measured (Baiardi, Puglisi and Scabrosetti, 2016). Consumer perceptions on the quality of food are, on the other hand, based on the attitude of the consumer to the consumption of food, and rely on issues such as hunger satisfaction, taste, convenience, appearance and its convivial aspects (Baiardi, Puglisi and Scabrosetti, 2016). For the food scientist, food quality has been defined as “the degree of excellence” which then involves attributes such as taste, appearance and nutritional content (Potter and Hotchkiss, 1995). Food quality therefore includes the attributes that influence a product’s value according to a consumer and therefore the degree of excellence thereof (FAO/WHO, 2003). The value of food is in many cases also measured on the price thereof, and although also based on the perception of the consumer, valued as affordable and fair to what was purchased and experienced (Baiardi, Puglisi and Scabrosetti, 2016).

The term ‘food safety’, according to ISO 22000 (2005), is defined as ‘the concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use’ and it is explained further by a note stating that ‘food safety is related to the occurrence of food safety hazards and does not include other

health aspects related to, for example, malnutrition'. ISO 22000 (2005) then goes further in defining a food safety hazard as a 'biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect'. Food safety hazards referred to by ISO 22000 (2005) also include allergens. ISO 22000 (2005) takes the definition of a food safety hazard into a bit more detail by explaining the term 'hazard' which is not to be confused with the term 'risk'. The concept then for food safety means 'a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization, absence from work, etc.) when exposed to a specific hazard'. Also, commonly known as risk analysis which involves risk assessment focusing on hazard identification and exposure characterization, risk management, which assists with decision-making in risk reduction methods and risk communication, which means educating the public on food safety hazards, their risks, uncertainties and the interventions to reduce these risks (Unnevehr, 2015).

The terms 'food safety' and 'food safety hazard' were adopted by the International Organization for Standardization (ISO) from the document developed by the Codex Alimentarius Commission (CODEX) (ISO 22000, 2005; CAC, 2009). Food safety, as seen by the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO), part founder of CODEX, is defined to be the characteristics of food that make food safe to eat and therefore prevent the onset of a food-borne illness. Food safety is therefore seen to be pertinent to the food safety hazards that make food harmful to the health of the consumer (FAO/WHO, 2003).

For the consumer, food quality may therefore mean the food product's value with taste being the highest scorer whereas food safety may in some way mean the same thing seen as something being part of its value. The safety of food is somehow perceived by consumers as less important, and achieving the second lowest score in a food quality survey conducted by Baiardi, Puglisi and Scabrosetti (2016).

For the food scientist, on the other hand, the quality and food safety characteristics of food mean different things and will significantly influence the way foods are produced, processed, distributed and displayed, especially in accordance with their intended use. Food is managed by food professionals through the application of

management systems as a tool to operationalize goals. Goals are generally based on achieving consumer acceptability, consistency, legality and safety of the food handled and applied as the minimum 'have to' requirements in a concrete measurable fashion with specific noted end points of achievement (Overbosch and Blanchard, 2014). Food safety management systems (FSMSs) involve the general quality management practices noted by ISO 9001 (2008), a food safety risk assessment model referred to as a hazard analysis and critical control point (HACCP) and the basic principles of hygiene, commonly referred to as prerequisite programmes (PRPs). These are all facets of the combined management of quality and food safety that need to be considered together to achieve the 'true value' of a food product (Overbosch and Blanchard, 2014).

## 1.2 Global perspectives on food-borne disease and the role of food safety management systems

The globalization of the food trade has created opportunities for developed and developing countries to be supplied with various types of foods based on not only a demand for a greater variety of food but also a desperate need in support of feeding a nation overwhelmed by food shortages.

The globalization of the food trade phenomenon has aided nations in supplying food to those in need but has also affected a considerable number of consumers worldwide as a direct consequence from consuming food that is contaminated with food safety hazards (Bricher, 2009). Food safety risks had been identified as an aspect that contributes to the burden of food-borne disease in developing countries and has recently been identified as an important public health issue (Unnevehr, 2015). The presence of food safety hazards in food at the point of consumption is caused by improper or uncontrolled food handling practices. These practices include activities derived from agricultural methods, poor hygiene throughout the food chain where food is handled, processed, stored, distributed and prepared, the lack of preventive controls applied during food handling and processing processes, misuse of chemicals and the application of overseen things such as contaminated water or raw materials used (FAO/WHO, 2003; Kirezieva et al, 2013; Shukla, Shankar and Singh, 2014).

According to reports of the WHO, food-borne diarrhoea is one of the most common food-borne diseases worldwide with an estimated 2.2 to 4 million cases per year with deaths reaching up to 2.2 million. In developing countries, it is estimated that 1.8 million children under the age of five die of food-borne diarrhoeal diseases where an estimated 70% of these deaths are caused by food-borne pathogens (FAO/WHO, 2004; Bricher, 2009; Unnevehr, 2015; Wills et al, 2015). It is further estimated that in developing countries, yearly one in three consumers are affected by a food-borne disease derived from microbes and their toxins. This number excludes food-borne diseases caused by natural-occurring or man-made chemical contaminants such as aflatoxins, acrylamide, furan or dioxin (Bricher, 2009). Aflatoxin exposure, for example, has been associated with liver cancer, immune suppression, higher rates of illness and child stunting (Unnevehr, 2015).

Statistics in the United Kingdom (UK) estimate a million cases of food-borne diseases every year leading to 200 000 hospitalizations and 500 deaths while in the United States one in six of the population is estimated to be affected by a food-borne disease leading to 3 000 deaths annually (Wills et al, 2015). In 2011, 1 865 cases of typhoid fever were reported in Zimbabwe alone, averaging between 30 and 50 new cases a day (Macheka et al, 2013). In 2008, also in Zimbabwe, 92 000 cases of cholera was reported which led to 4 000 fatalities (Macheka et al, 2013). Statistical reporting is also now starting to show that the handling of food at home is often a reason for the onset of a food-borne disease. Statistics of 12 to 17% of general food-borne outbreaks reported in England and Wales suggest that they may have originated from home, while salmonella and campylobacter infections may account for 50 to 80% of such incidents. Studies leading to this reporting indicate that these incidents may be due to the non-adherence to food safety recommendations for the handling of a food product, but that they may be difficult to pinpoint based on all the variabilities in a home kitchen leaving the possible non-compliance aspects as problematic towards food-borne diseases (Wills et al, 2015).

Food-borne diseases caused by food and water contaminated with food safety hazards present a threat to public health with a further impact on the social significance of the diseases caused. Food-borne diseases can significantly affect the health and well-being of the consumer, but more so have an impact on the economic

consequences of the individual, his/her family, community, business and as a whole on a country. Food-borne diseases frequently occur as isolated incidents, but when they escalate into outbreaks affecting large numbers of people they place a significant burden on a country's healthcare system, and therefore impact negatively on economic productivity. The UK, according to 2013 reports of the Food Standards Agency, spends UK£1.8 billion per annum on food-borne disease related incidents (Wills et al, 2015). Statistics available between 1996 and 1999 reflected the cost of food-borne diseases in the United States due to seven specific microbiological pathogens to range between US$6.5 billion to US$34.9 billion. In more recent years food-borne diseases resulted between US$14 billion and US$152 billion in loss of productivity and life in the US (Unnevehr, 2015). In England and Wales the medical costs and the value of lives lost from five food-borne infections were estimated at UK£300 million to UK£700 million annually. The cost of an estimated 11 500 cases of food poisoning per day in Australia was estimated at AUD$2.6 billion annually. The economic impact of a *Staphylococcus aureus* outbreak in India was, based on income per capita, reported as higher than a similar case in the United States (FAO/WHO, 2003).

Food can therefore be a risk to the consumer and also to the country and needs to be controlled to prevent the prevalence of food-borne diseases, especially with the increased demand in food globalization.

### 1.3 Food trade as a means to support sustainable development

Trading in food is one of the market access points for developing countries. Market access means supplying food to the local market and opportunities to explore the trade of food in international markets. The growing, farming, harvesting, processing and handling of food are skills applied by people for centuries and in many cases are a general livelihood activity. A livelihood activity is applied by people in developing countries on small and medium scales and comprises activities which can be transformed into market access opportunities for individuals and countries in support of national challenges, such as public health, nutrition, elevating poverty, improving sustainable development, market access, and chronic vulnerability in regard to food security (Kebebe et al, 2015).

Innovation in the consistent and safe production and trading of food is a motivation set by world trading partner needs based on the world's population which are reaching staggering figures. Food demand is an ongoing topic of discussion at all levels of governments globally leading to finding innovative means to balance demand and supply to an affordable price. These demands are driving the supply of food to become based on variety, convenience, quality, consistency, safety and year-round supply. The competition between suppliers to adhere to these demands is leading to new business methods such as direct buying contractual arrangements with producers, centralized procurement centres, private brands, standards and compliance requirements (Hatanaka, Bain and Busch, 2005). Compliance with these demands and requirements by the food handler may then become an initiative to sustain the supply of its food product.

The growing need for sustainable development and in general the eradication of poverty by governments and world trading partners created opportunities for the development of many small food-producing businesses. This phenomenon is seen in both developed and less developed countries leaving small food-producing businesses playing an integral role in all market economies (Taylor, 2001). The Department of Trade and Industry of the UK already in 1999 estimated that small food-producing businesses accounted for 99% of all food operations in the UK, employed 50% of the workforce and contributed to 38% of turnover (Taylor, 2001). The role of small food-producing businesses can therefore not be ignored. Their contribution to the risk of the supply of unsafe food can therefore equally not be ignored and this has placed them in the same predicament as medium and large food-producing businesses, i.e. the institution of official food safety controls.

The term small business can further be expanded to what is referred to as a less developed business, meaning a business that does not have the means or technical know-how to apply certain business activities, i.e. in this case an official food control system (FAO/WHO, 2004).

Global food demand may not be the only challenge, as food needs to be supplied at an affordable price to the middle to lower income groups. The demand for safe food is similarly challenging. The impact of a food-borne disease on a developing

country's economy may be detrimental, financially and resource wise, not only on a national level but also in terms of its possible influence on global food supply.

### 1.4 Food safety control as a technical barrier to trade

Food safety control has also over the years been challenged by a rise in the outbreaks of food-borne diseases, and this is despite controls employed by governments, food traders and food handlers (Bricher, 2009; Wills et al, 2015). This unexpected ongoing occurrence may be due to new and emerging food safety hazards, especially microbiological pathogens, rapidly changing food production, processing, handling and marketing technologies, the development of science-based food control systems focusing on consumer protection, demands for international food trade, changes in lifestyles, urbanization, and the growing awareness of consumers regarding food safety and their demand for access to information on food (FAO/WHO, 2003). The globalized food trade has also placed pressure on the traditional food quality and safety compliance verification methods where markets are now forced owing to the demand and needs for product diversity to conduct compliance controls through third-party inspections or certifications, rather than governmental governance (Hatanaka, Bain and Busch, 2005).

Legal requirements set by governments as mandatory controls as well as standards set as either mandatory or voluntary controls have been used over the years to support the efforts to control food-borne diseases. The use of standards, through a national and international process of standardization, has developed into a common means for a food handler to ensure that food products are consistently produced to a set norm. This norm, for the food handler, has transformed over the years from being quality focused to being food safety focused and has now developed into a type of governance for the supply of food, especially trading of food across borders (Olper, Curzi and Pacca, 2014). The application of these standards, as shown in a study conducted by Olper, Curzi and Pacca (2014), indicated that their impact on the cross-border food trade could act as a non-tariff barrier to trade leading to constraints of a country' export, especially standards relating to sanitary and phytosanitary (SPS) measures, but could also on the other hand lead to export gains based on the upgrade of products through modernization. Application of standards turned into a competitive edge towards the food trade and the access to the cross-

border food trade, and the relationship towards evidence of application of standards has placed pressure on the food handler to have a balance between competition, innovation and now also safety (Olper, Curzi and Pacca, 2014).

Food safety control factors to ensure the adherence to SPS measures have placed underlying pressures on food suppliers to ensure that the risk of supplying unsafe food is not only minimized, but also controlled. This has led to the development of food safety control demands by food users including consumers, especially those users at the end of the food chain, the food retailers. Retail-driven food safety control demands found their way back into the food chain through the demands of compliance to 'self-owned' standards and requirements. These demands have also as early as the start of the 2000s transformed the traditional methodology for governance by government of quality and safety compliance to a more demanding third-party inspection and certification compliance methodology, which added to the demands placed on the food handler (Hatanaka, Bain and Busch, 2005). Demands which led to the development of various trade binding food handling requirements, private standards and compliance requirements.

The number of 'self-owned', or private standards and their particular food handling requirements places a burden on the food handler because of the different views on food safety controls and how a particular food retailer would want the food handler to produce a food product. These standards are typically set more stringently and comprehensively than the national or international standards set by standardization bodies (Hatanaka, Bain and Busch, 2005). The variances in private standards are also adding to the cost of food handling in terms of the cost of compliance, thereby impacting negatively on the ability of the food handler to reach a target market. Compliance with these private standards is turning standardization into a competitive market battle suggesting that if the food handler finds it difficult to demonstrate compliance with a private standard, the food product may not be displayed or sold by the retailer or food trader, this suggestion again raising a barrier to trade (Olper, Curzi and Pacca, 2014).

The demand for compliance with food safety controls applies to all sizes of food businesses, whether urban, small, less developed, and medium to large and/or

multinationals. Evidence of continued compliance with these controls is what stifles the sustainability of a food business to provide safe food to a food retailer or food trader. Obstacles to continued compliance are often based on the ever-changing food safety control requirements and standards and the inability of food businesses, especially small businesses, to apply the required resources towards this compliance. The food safety control demands by retailers are further complicated by regulatory food control demands and this places a further burden on the food handler and its ongoing pressures to remain sustainable.

### 1.5 Africa, a developing continent

Africa, hosting a population of more than 842 million people, in the past decade has been regarded as the continent with the world's fasted growing economies. Statistics indicate that sustainable economic growth is influenced prominently by cross-border trade (Jerven, 2014). New economies help to alleviate poverty-stricken households, populations and to improve human development through the sustainability of manufacturing and retail industries. Economic growth, however, needs to be sustained, especially on a continent stricken with droughts, floods, political uncertainty, conflict, low household incomes, food insecurity, HIV/Aids, disease, malnutrition, seasonal hunger, and the vast amount of loss of life and livelihoods due to these impediments. Impediments are seen to affect all generations of inhabitants of this continent (UNDP, 2012).

A contentious topic at various governmental and organizational assemblies is the chronic food insecurity of the continent. Food security is often alleviated through the adoption of various types of food aid programmes where food items are supplied and/or the means, i.e. job creation that enables individuals to purchase at least the basic food items (Sabates-Wheeler and Devereux, 2010). The question is raised, food safety versus food security, which one takes preference in a developing continent? The 1996 World Food Summit declaration states, 'Food security exist when all people, at all times, have physical, social and economic access to sufficient, safe, and nutritious food to meet their dietary needs and food preferences to meet their active and healthy life'. Food safety was also recognized as one of the enabling environments for reducing hunger and malnutrition during the 2014 Framework for Action adopted at the Second International Conference on Nutrition. Food safety

therefore forms an integral part of food security (Unnevehr, 2015). Food needs to be safe to prevent a food-borne disease from leading to acute and possible chronic illness reducing the bioavailability of nutrients in particular already vulnerable groups. Food contaminated with food safety hazards will certainly lead to the reduction in the availability of food to those food insecure populations (Unnevehr, 2015).

Many of the households and informal retail in many countries on the continent rely on smallholder farmers to supply food, something that is influenced by the deterioration of rural infrastructure and the weakening of farming practices. This is leading to the stagnation of growth of food supply systems within many countries on the continent, which will have a negative impact on the sustainability of a growing economy and elevation of poverty (UNDP, 2012). Stagnation of the food supply systems in a country might put pressure on the food handler and/or even the retailer to apply farming practices not conducive to safe food production, which will have to be understood and implemented by those dealing in these food supply systems.

The continent also find itself in a position where inferior products are brought into countries based on the conditions of trade stemming from the conduciveness of smuggling and fixed commodity prices leading to traders circumventing official channels for entry or exit of products. Informal trade, which can be legitimate or illegitimate, is still seen as a legitimate commerce in accordance with the World Bank where traders would pass through official border posts paying their duty on imports, which is perceived to be an informal trade and is therefore not officially recorded based on the small amount of goods associated with the transactions (Jerven, 2014). The World Bank reports further in the study conducted by Jerven (2014) that the informal legitimate trade leaves these entrance goods without traceability, an audit trail or ways to verify what was imported, by whom and how much was paid, essentially causing a food safety dilemma. These trading ways could be the result of a need for trade to sustain life and growth within an economy being pressured to perform in equal measures to developing countries. In addition to these challenges, many African traders and consumers still need to conceptualize the concept of quality and safety, especially when it comes to food. African governments are still failing to protect their citizens from fraudulent trade and efforts should be made to

assist them to enter new markets based on international standards, regulations and best international practices (Musinguzi, Jenders and Diergardt, 2011).

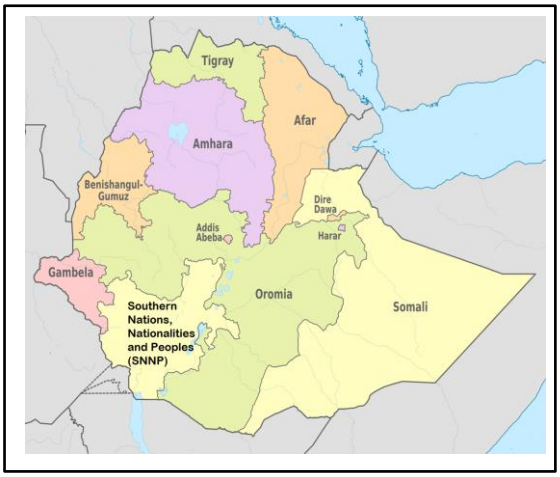
## 1.6 Ethiopia and its challenges

National flag of Ethiopia

Ethiopia, situated in the horn of Africa, is the ninth largest country in Africa and has a population of over 93 million people. It is the most populous landlocked country in the world and the second most populated nation in Africa.


Location of Ethiopia on the African continent

Ethiopia is the oldest independent country in Africa and also one of the oldest sites of human life known to scientists where its roots can be traced back to the second millennium before Christ. It is home to a multilingual society with around 80 ethnic groups spread over 11 regions leading to more than 80 languages and over 200 dialects. Amharic or Amharigna is the official language of Ethiopia.




Regions of Ethiopia

Approximately 17% of the population lives in the urban areas of Ethiopia. The range of altitude between 100 meters below sea level in the Dallol Depression of Afar to mountain peaks of over 4 000 meters above sea level in Semien creates a moderate temperature rarely exceeding 20°C thereby creating a pleasant subtropical to tropical climate. The Afar regional state in the east lies below sea level and is considered the hottest place on earth with temperatures reaching up to 50°C.

Rainfall in the highlands occurs in two distinct seasons named the ‘small rains’ which is between February and March and the ‘big rains’ which is from June to September with heavy rainfalls in most of the country during June, July and August. The lowlands have their rain in March to May and then again in October to December. The overall pleasant climate creates a quite diverse landscape from fertile land in the west to semi-deserts in the east, tropical forests in the south, numerous rivers and lakes, lowlands, the largest continuous mountain ranges, and the largest cave in Africa. Ethiopia’s rivers are the main source of the Nile, the longest river on earth.

Ethiopia’s calendar is based on the ancient Coptic calendar, also known as the Ge’ez calendar, and is seven years and about three months behind the Gregorian calendar. It is divided into 12 months of 30 days each with the remaining five or six days making up a thirteenth month. The Ethiopian New Year is on the 11 or 12 September in the Gregorian calendar and the months start mostly between the seventh to the eleventh day of the month. Ethiopians use a 12-hour clock, with a cycle running from 1 to 12 starting at dawn to dusk and the second cycle from dusk to dawn. The start of a day is at dawn.

Ethiopia is the origin of the coffee bean, it has nine United Nations Educational, Scientific and Cultural Organization (UNESCO) World Heritage Sites, and still to today, uses the oldest alphabets in the world. The National Museum of Ethiopia holds the oldest human skeletons, named Lucy that is estimated to be 3.4 million years old and Ramidus that is estimated to be 4.4 million years old.

Ethiopia is described in the writings of the Greek historian Herodotus of the fifth century BC as well as in writings of the Bible’s Old Testament where the Queen of Sheba’s visit to Jerusalem is described where ‘she proved Solomon with hard questions’ and where legend describes the asserts of King Menelik

Rock-hewn churches of Lalibela, Ethiopia

being the son of the Queen and King Menelik was the founder of the Ethiopian Empire.

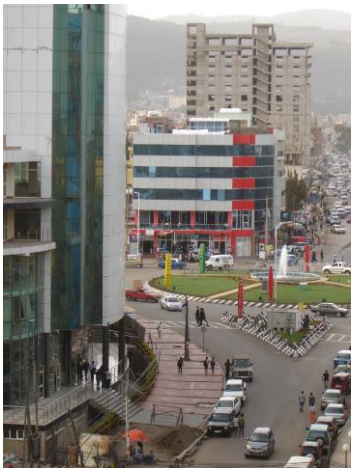
Axum, the remains of the Queen of Sheba's palace, can still be seen today and hosts many other extensive historical sites which include the Ark of the Covenant brought to Axum from Jerusalem by King Menelik.

Ruins of Aksum, Axum, Ethiopia

The local currency is the Ethiopian birr which is made up of 100 cents (FDRE, n.d. a; FDRE, n.d. b).

Ethiopian folk refer to their country as 'Ethiopia, the country with 13 months of sunshine'.












A typical day in Addis Ababa, Ethiopia

The main source of export for Ethiopia is agricultural products such as coffee, oilseeds, pulses, cereals, flowers, skins and hides. Ethiopia is seen to hold the largest number of cattle in Africa, and in terms of the manufacturing industry with food processing to be the leading sector (FAO/WHO, 2005). Food production therefore plays and integral role in Ethiopia's sustainable development and economic growth.

Food safety controls in Ethiopia are shared by the Ministry of Health, the Ministry of Agriculture, the Ministry of Industry, the Ministry of Trade, the Environmental Protection Agency, and the Quality and Standards Authority of Ethiopia (QSAE), including various other stakeholders such as Federal and Regional Governmental Bodies, Research Institutions, the Ministry of Education, food manufacturers, distributers and hotels (Ayalew, Birhanu and Asrade, 2013). Little guidance on food safety is given in Ethiopia because a comprehensive food safety policy for Ethiopia has not yet been developed (Ayalew, Birhanu and Asrade, 2013). However, the aspects of communicable and infectious diseases are dealt with in policies such as the National Health Policy that focuses on the prevention and control of major health problems in the country, including those that may be derived from unsafe food (FAO/WHO, 2005). A Public Health Proclamation, No 200/2000, has been issued by the Ethiopian Government and deals with issues of food safety which is supported by regional regulations relevant to regional content (FAO/WHO, 2005). Further food safety related legislation includes The Meat Inspection Amendment Proclamation No 81/1976 and The Meat Products and Animal Diseases Prevention Control Proclamation No 267/2002 (FAO/WHO, 2005). The Ethiopian Food, Medicines and Health Care Administration and Control Authority, which based on the Food, Medicines and Health Care Administration and Control Regulation No 189/2002, was also established to assure the quality of food, safety, efficacy, quality and proper use of medicines, competence and ethical practice of health professionals, competence of health and health-related institutions and services (Ayalew, Birhanu and Asrade, 2013). Two new proclamations, Trade Practice and Consumer's Protection, Proclamation 685/2010 and Commercial Registration and Business Licence, Proclamation 686/2010, were recently announced in support of food safety assurance in the country (Ayalew, Birhanu and Asrade, 2013).

National and International Standards that support food safety are prevalent in Ethiopia through the development and adoption of standards by the QSAE (FAO/WHO, 2005). The QSAE is governed by the Standards Development Proclamation No 102/1998 and is given the scope for the development of standards which can be applied voluntary or as technical regulations under the Regulation No 13/1990 (FAO/WHO, 2005). More than 450 standards relating to food have been published by the QSAE, some being technical regulations which are then enforced through inspection or testing by the QSAE in support of food safety controls (FAO/WHO, 2005). The QSAE therefore has the power to, by prior notice, close factories or business undertakings or to cease operations or to ban the movement of products which do not comply with these technical regulations, commonly referred to as compulsory specifications (FAO/WHO, 2005). The basis of these specifications is derived from CODEX text which supports a more scientific enforcement tool towards aspects such as pesticide residues, and food additives. (FAO/WHO, 2005).

The Animal and Plant Health Directorate, under the auspices of the Ministry of Agriculture and Rural Development, is responsible for implementing and regulating the SPS measures in Ethiopia implying the application of regulatory controls for the quality and safety of all animal and plant products and other inputs such as the registration of pesticides, fertilizers and seeds through the safeguarding of agricultural trans-boundary animal diseases, migratory insects, plant pests, grain-eating birds, noxious invasive weeds and plant diseases (Ayalew, Birhanu and Asrade, 2013). Regulatory food and food establishment inspections, including quarantine border inspection points are shared between the meat inspector veterinarians, senior and assistant meat inspectors, health inspectors (sanitarians) and compulsory specification inspectors (FAO/WHO, 2005). Inspections cover the sanitation of slaughter houses, processing plants and food establishments in terms of overall environmental health services, and compliance are enforced through the power given to the inspector for the closure of food businesses on evidence of non-compliance with rules, regulations and standards (FAO/WHO, 2005). Voluntary inspections are conducted by the Ethiopian Conformity Assessment Enterprise (ECAE) (formerly part of the QSAE) through the application of certification of management systems around agriculture, fisheries, food and beverages and are

supported by the testing laboratories of the ECAE in terms of food chemical and microbiological testing.

Ethiopia, like most developing countries, does not have an effective organizational structure or recourses available to conduct surveillances of food-borne diseases (FAO/WHO, 2005). The actual incidence and impact of food-borne diseases in Ethiopia are therefore unknown, although already in 2004, the Ministry of Health published information indicating that the 10 leading causes of visits to health institution outpatients included all forms of diarrhoeal diseases and indications of parasite infestations that may have directly or indirectly been derived from food (FAO/WHO, 2005). Surveys conducted in 2003 and 2004 in the major regions of Ethiopia indicated the prevalence of diseases such as ascariasis, typhoid, dysentery, tapeworm, tuberculosis, and infectious hepatitis. During 2007 and in 2009 cases of acute watery diarrhoea leading to several deaths were reported in particular regions (Ayalew, Birhanu and Asrade, 2013). Food-borne disease syndromes reported by the Ministry of Health included ranges of diseases such as amoeba, gastroenteritis or duodenitis, dysentery, typhoid, intestinal parasites, diarrhoea, and helminthiasis, all indicating the severe impact of unsafe food in Ethiopia (Ayalew, Birhanu and Asrade, 2013).

Further pressure towards not only the knowledge or technology of food handling or processing, but also the control of food-borne disease may arise from food-aid programmes. These include the Ethiopian Productive Safety Net Programme and innovation initiatives such as the dairy innovation systems which are instituted in Ethiopia, and which are similar to programmes in various other African countries in support of economic development and growth (Kebebe et al, 2015). The Productive Safety Net Programme, for example, is a programme noted as another chronic need for food aid, which in 2006 supported nearly 11% of the population with food aid which amounted to approximately 8.3 million of the 71 million people in Ethiopia. The programme involves the support of food aid through unconditional cash transfers and/or the supply of actual food aid. In some cases, the provision of labour is also given and all of this is done in support of humanitarian and poverty relief. The supply of cash transfers, which is influenced by inflation in terms of the actual purchase of items, allows the individual to purchase the minimum food needed, i.e. a quantity of

a staple cereal such as maize or rice or the equivalence of a food-aid ration which could then include maize, beans and cooking oil (Sabates-Wheeler and Devereux, 2010). All of these food products should be controlled through good food manufacturing practices as a purchased commodity. The supply on the other hand of the actual food aid through such a programme loads the burden of food quality and food safety controls if the origin, contents, handling and distribution aspects of the products are unknown. For programmes such as the dairy innovation systems, support from governmental role players such as the Ministry of Agriculture, which has been given the mandate to provide technical training and services such as the supply of veterinarian drugs and services to smallholder farmers, in many cases in terms of the quality of personnel, is not effective in supplying the needed technology knowledge and services (Kebebe et al, 2015). Technology knowledge which could lead to the initiation of food safety controls might therefore be lacking and consequently not dealing with food safety as part of these types of programmes or innovation systems.

A collaboration of activities by various institutions such as the Ministry of Health, the Ministry of Agriculture and Rural Development, the QSAE and its supporting enterprises, the Ministry of Trade and Industry, and the Ethiopian Manufacturing Industries Association of Ethiopia has since 2002 applied efforts together under the auspices of a Technical Committee for Food Safety Assurance and under the leading hand of the United Nations Industrial Development Organization (UNIDO) to control food safety activities through the establishment of a National Food Safety Council (FAO/WHO, 2005). This council also involves research institutes, industry, consumers and higher learning institutes that are working together to strengthen food regulation within the country (FAO/WHO, 2005).

Another obstacle facing Ethiopia in its effort to strengthen food control is the availability of competent testing laboratories (FAO/WHO, 2005). The demand by importing countries and imported foods to test for, inter alia, the presence of chemicals, pesticide residue, aflatoxins, animal chemical and toxicological residue, and pathogenic microorganisms is putting further pressure on the mandate for controlled food regulation (FAO/WHO, 2005). Food testing is carried out by the Ethiopian Health and Nutritional Research Institute, the Microbiology Public Health

Laboratory, the Public Health Chemistry Laboratory, Regional Veterinarian Laboratories, the National Animal Health Research Centre, and the QSAE, however, all seem to be burdened by understaffed and poorly equipped facilities (FAO/WHO, 2005). A programme for upgrading these testing facilities has been in operation since 2004 and is supported by international aid organizations and sponsorships such as UNIDO, and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) (FAO/WHO, 2005).

The food industry in Ethiopia has recognized the need for the application of food safety practices to satisfy the international demands of food safety and quality assurance of products (FAO/WHO, 2005). Efforts to sensitize the industry to meeting these demands is again a collaboration of institutes such as the Consumer Association, the Ethiopian Manufacturing Association, Regulatory Authorities and projects such as the UNIDO food safety project where awareness is increased on various levels towards reaching food safety control (FAO/WHO, 2005).

The challenges faced by Ethiopia towards effective food control are not so much different from the challenges found in similar developing countries. Typical major challenges remain the effective coordination and clearly demarcated responsibilities of regulatory authorities, inadequate food-borne disease surveillance, lack of food control enforcement, testing facility capabilities, knowledge of standards, regulations, good practices, science and food manufacturing technologies, and the international demands for the supply of safe food. These challenges seem to overwhelm the potential of Ethiopia to produce and export food-based products which will support the need for sustainable development and economic growth.

## 1.7 Rationale

### 1.7.1 Problem delineation

Food remains the only common need for humanity to survive. Unsafe food, as shown by literature, poses a risk to the health of the consumer and a significant burden on economies already restricted by various societal demands.

Food control within a country and more specifically towards the exporting and importing of food became a barrier to trade when the country trading in food did not or could not ensure that the food moving across borders met the minimum quality, hygiene and safety standards. Trading barriers were also increased by the variances in food control standards and regulations required by food traders impacting severely on the continued sustainability of the food handlers to consistently produce safe food.

Methods for the predetermination of the risk of food towards the safety of the consumer had been developed in the early 1960s and became a prerequisite for the trading of food, especially across borders. This prerequisite is commonly referred to as HACCP and involves a scientific study of the presence and risks of food safety hazards that may lead to food-borne diseases at the point of consumption.

The World Trade Organization's (WTO) agreements for trade identified and noted the need for the supply of safe food, especially with the trading of food across borders. These agreements require the government of a country to set up an infrastructure that will support the demands for safe food trade and therefore the creation of institutions, regulations and standards towards this concept.

A predicament developed when developing countries did not have the means to develop and apply the required food control systems. This dilemma then became a barrier to trade for developing countries wherein the food handlers were not able to sell the food produced based on the lack of evidence of verified quality, hygiene and safety standards by authorities and related institutions.

The verification of the quality, hygiene and safety features of food is to be carried out by competent authorities and institutions, and these competencies had to reflect compliance with the requirements of international standards and best practices, an obstacle faced by many developing countries.

Various forms of capacity building projects under the auspices of the WTO programmes for support towards developing countries became the solution to the needs for competencies required to verify the quality, hygiene and safety features of

food. These capacity building projects focuses on the support towards the development of a national quality infrastructure (NQI) required as part of the membership agreements of the WTO. Donor organizations support these capacity building projects through the placement of technical experts in environments where work is to be carried out based on the needs set by the donor receiver, referred to as the beneficiary. Expert work is designed around a terms of reference (ToR) which stipulate the needs, activities and specific outputs of a project and which are developed and agreed upon between the beneficiary WTO projects office. A project coordinating organization is then selected and appointed based on a tender process instituted by the donor organization. Technical experts are then sourced, selected and placed into the working environment of a specific capacity building project in accordance with the requirements of the ToR.

The effectiveness in the provision of these capacity building projects towards the successful development, deployment and sustainability of a NQI or, in this study's case, the conformity assessment aspects of a NQI, is questionable. Achieving the goal in building a sustainable capacity within the beneficiary has to be designed into accurate and detailed project plans, where after various ToR documents will support the project owner in reaching its objectives. The precision of the ToRs of the overall project is questionable based on the possibility of it not actually reflecting the needs of the beneficiary mainly due to the extensive time, sometimes up to two years it takes for the generation of the ToRs and the sourcing and selection of an expert matching the ToR. This may overall stifle the successful implementation of a sustainable capacity building project which is in many cases further restrained by time and funds allocated to the project as a whole.

### 1.7.2 Study aim

The aim of this study was to assess the level of accomplishment of the implementation of a sponsored NQI capacity building project towards building capacity on an FSMS certification scheme in Ethiopia over a two-year period and its long-term sustainability through achieving and maintaining an accredited status.

The sponsored capacity building project selected for this study aimed to support the sustainable development of a management system for the ECAE on the

implementation, application and maintenance of an accredited FSMS certification scheme for the Ethiopian food industry.

### 1.7.3 Objectives and chapter layout

The objectives of the study included the following:

a. To conduct a technical review of the contributing features needed to establish and apply a NQI in support of food safety control through the application of a FSMS certification scheme for a developing country. (Chapter 2)
b. To perform a gap analysis of the capacity of the selected certification organization in Ethiopia to provide an accredited FSMS certification scheme to the Ethiopian food industry. (Chapter 3)
c. To conduct a comparative progress assessment of the Ethiopian certification organization who received the donor NQI capacity building project over the two-year period. (Chapter 4)
d. To conclude on the effectiveness of donor funding interventions in successfully establishing strategies in Ethiopia, focusing on accredited FSMS certification capacity building. (Chapter 5)

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# CHAPTER 2

# ACCREDITED FOOD SAFETY MANAGEMENT SYSTEMS CERTIFICATION IN ETHIOPIA: A TECHNICAL REVIEW

For submission, either partially or in full to the journal: Food Reviews International (ISSN:87559129)

## 2.1 Introduction

Trade as a concept is seen as an activity where goods or services are sold to make a profit (Law, 2009).

Developing countries play an active and increasing role in trade where their focus is moving from a small household bartering model for family sustainability to a more market- or inland-relevant trade model. This is leading governments to a future goal setting of achieving an impact on the global economy through their increasing need to trade as a vital tool for their development and growth as an economy. Entering the global market is placing a strain on producers through the pressure of compliance with standards and regulations. These standards and regulations in some cases differ from country to country, and that, in addition to self-constraints and obstacles to reach the market, leads in many cases to 'excuses for protectionism' and therefore increased obstacles to trade (WTO, 2011). However, when trading in food, a country needs to ensure that the food supplied to its consumers are safe to eat and that ways and means are developed and applied to ensure this safety.

Encouraging trade supports economic growth, alleviates poverty, expands social development, and elevates knowledge and skills of those who inwardly want to make a living and sustain families. Sustainable trade can only be guaranteed through the institution of a national framework in a country based on technical regulations, metrology, standards and conformity assessment practices, referred to as a country's NQI.

This chapter puts forward a technical review of the framework required for a NQI and therefore forms the foundation of the study towards accredited food safety management certification in Ethiopia. This technical review focuses on the various pillars of a NQI, its origin, interactions and needs of the various role players supporting the NQI and leading to the trade of safe food through the building of capacity of specific role players within this framework.

## 2.2 The World Trade Organization and its agreements

> *'The World Trade Organization (WTO) was born out of negotiations; everything the WTO does is the result of negotiations.'* (WTO, 2011)

The WTO was established on 1 January 1995 through the Uruguay Round trade negotiations of 1986 to 1994, and even earlier in 1948, under the General Agreement on Tariffs and Trade (GATT). It is based in Geneva, Switzerland, and aims to support trade through setting a forum for trade negotiations, handling trade disputes, monitoring national trade policies, supplying technical assistance and training for developing countries, and encouraging cooperation with other international organizations (Steyn, 2010; WTO, 2011).

The operations of the WTO are based on membership from governments of trading nations. Its work is mostly based on negotiations to liberate trade through lowering barriers to trade but then also in some cases to support rules for maintaining barriers to trade to protect consumers and to prevent the spread of disease. It bases its work on the principles of trade which are to support a trading system that is without discrimination, freer, predictable, more competitive and more beneficial for the less developed countries. Members are responsible to make decisions and membership is represented by ministers, ambassadors or delegates of member countries. Meeting are conducted at least once every two years and decisions are based on consensus of members (WTO, 2011).

The WTO further bases its work on rules which are in the format of legal agreements, negotiated and signed by its members. These agreements provide a legal foundation for international trade and can be contracts binding governments to set and implement policies within the boundaries of the agreements. The universal goal for setting up these agreements is to support businesses to trade and then for governments to meet their social and environmental objectives. The overall focus therefore is to eliminate unnecessary barriers to trade (Steyn, 2010). Several agreements have been set up to deal with trading matters, such as agriculture, clothes and textiles, telecommunications, industrial standards and product safety, food sanitation regulations, intellectual property, and banking. Two specific agreements of interest to this study were established to protect human, animal and plant life and health, i.e. the SPS agreement which deals with food safety and animal and plant health standards and the Technical Barriers to Trade (TBT) Agreement

which in turn deals with regulations, standards, and testing and certification procedures (WTO, 2011).

The SPS agreement allows countries to set up their own standards although the use of international standards, guidelines and recommendations is encouraged. In terms of international standards, the annexure to this agreement refers to the CODEX standards for food, the International Animal Health Organization for animal health and the Food and Agricultural Organization of the United States (FAO) Secretariat of the International Plant Protection Convention for plant health. Regulations set by countries need to, however, be based on science and would need scientific justification if the measures set are higher than general standards applied. The setting of higher standards should be based on appropriate risk assessments and scientific evidence and may even be supported by a temporary precautionary measure to support the concepts of 'safety first' should there be a certain level of uncertainty, scientifically. The application of different standards and therefore also different methods of inspection of products may create a barrier to trade. It is therefore agreed that if the exporting country can confirm that the measures are taken to ensure that the level of safety of the exporting product meets the levels of safety of the importing country, then the importing country is expected to accept the product based on its standards and methods of inspection or testing. The SPS agreement allows for the provision of control, inspection and approval procedures of products moving between countries and therefore also complements the application of the TBT agreement (WTO, 2011).

The TBT agreement on the other hand ensures that no unnecessary trade obstacles are created owing to the application of different standards and measurement applications based on country specific regulations, standards, testing and certification procedures. Countries have the right to adopt the standards they deem appropriate to ensure human, animal or plant life or health, to protect the environment or to meet other consumer interests. Although the application of international standards is encouraged, countries are not obliged to change their levels of protection. This agreement therefore sets out a code of good practice for governmental organizations that prepare, adopt and apply standards and the setting of their own regulations. Procedures applied to decide when a product is in

compliance with standards and regulations need to be fair and reasonable. This agreement also encourages countries to recognize one another's testing procedures, thereby implying that a product can be tested in its country of production against the importing country's standards or regulations. This further implies that manufacturers and exporters need to be able to have access to the standards and regulations of the importing country and therefore this agreement ensured that all WTO member countries establish a national point of enquiry that can supply information on the standards, regulations and possible inspection or testing methods of a product (WTO, 2011).

The agreements on TBT and SPS established by the WTO focus on the preparation, adoption and application of technical regulations and as a WTO rule are intended to be applied by governments to regulate their markets in a transparent manner.

The principles of technical regulations should be based on international standards. The reason for this is not only for harmonization purposes but also to have transparent rules for testing, certification and inspection. Transparency is achieved through accreditation and is intended to be achieved by competent bodies that carry out inspection, certification, testing and calibration activities.

Voluntary standards, applied to further and support trade, should be elaborated by competent and recognised standards bodies. Voluntary standards are applied to strengthen SPS measures, according to Annexure A of the TBT agreement, which includes all laws, decrees, regulations, requirements, procedures such as end-product testing, inspection, and certification. Approval procedures, quarantine treatments, provisions on statistical methods, sampling procedures, and methods of risk assessment are also described. Packaging and labelling requirements are included in the agreement and is intended to be applied in situations to protect human and animal health from risks arriving from additives, contaminants, toxins or disease-causing organisms in food. The protection of human life from plant- or animal-carried diseases, protection of animal and plant life from the introduction of pests, disease-causing organisms, the protection of a country from damaged caused by the entry, and the establishment or spread of disease all form part of the efforts to

set up voluntary standards and when required, technical regulations (Jongwanich, 2009; Neeliah and Goburdhun, 2010).

Signatory member countries of the WTO also have an obligation to provide for a National Notification Authority which should be a single governmental authority that will oversee the implementation of notification procedures of the WTO and which should notify the TBT and SPS Secretary of the WTO of approved technical regulations. Governments are therefore obliged to provide in advance notices on their new or changed SPS regulations in support of prevention of instituting a technical barrier to trade. A National Enquiry Point should be established by a member country that is responsible for handling enquiries on trade, standards and technical regulations and should provide the relevant enquired documentation to the interested party requiring information on the trade of products inland as well as cross-border (Sanetra and Marbán, 2007; WTO, 2011).

The WTO therefore contributes to the development of trade. Developing countries have been identified as a group that in particular needs support in the development of trade and therefore the infrastructure to support trade. Developing a country's ability to trade implies that a sustainable development and/or improvement of its infrastructure to support trade are required. This infrastructure is translated into a term referred to as a NQI. Capacity building projects became the means of developed countries as members of the WTO to support developing countries in the development and application of a NQI not only to support inland trade but also to support cross-border trade and therefore the overall growing of economies.

## 2.3 A National Quality Infrastructure (NQI)

A NQI refers to the characteristics of metrology, standardization, testing, certification (conformity assessment of management systems and products) and accreditation systems, and is required to protect the health, safety and environment of products which should comply with national verifiable standards. These characteristic activities could be executed by public and private institutions within a country which then overall and in combination operates within a set regulatory framework.

A NQI focuses on the support of technical competence and compliance with national and/or international standards and is mainly of a voluntary basis. Technical standards commonly referred to as regulations can, and should, be used by regulatory bodies for their compulsory applications so that duplication of requirements is avoided. Technical regulations and legal metrology are mainly regarded as compulsory whereas standards, industrial metrology and conformity assessment are regarded as voluntary. A NQI will give access to traceable calibrations, internationally recognized accreditations, compliance with international standards, traceability of national measurement standards, participation in international comparisons, and mutual recognition agreements with other countries regarding product trade (Sanetra and Marbán, 2007).

There are three main pillars that form the framework of a NQI as a key enabler of trade capacity building and economic development. These three main pillars are a National Standards Body (NSB), a National Metrology Body (NMB), and a National Accreditation Body (NAB) (ISO, 2006; Sanetra and Marbán, 2007; ISO/UNIDO, 2008; ISO/UNIDO, 2010). The components of a NQI are, however, interrelated and should be working actively together (Sanetra and Marbán, 2007; ITC, 2010). Thus, a measurement standard cannot be used without reference to a reliable measurement, measurements must be internationally standardized to prevent costly equivalents, products are tested to determine conformance with standards, and testing procedures should be standardized and rely on reliable measurements and accreditation, which are based on international standards. This is the process where all these activities become reliable and trustworthy, where national and international trade becomes easier, and technical barriers to trade are dismantled (Sanetra and Marbán, 2007). Figure 1 provides a schematic representation of the characteristics of a NQI, including an NFCS as a focus point to this study and then its integration with the various international forums supporting the credibility of a NQI. (Synthesis based on author's professional experience)

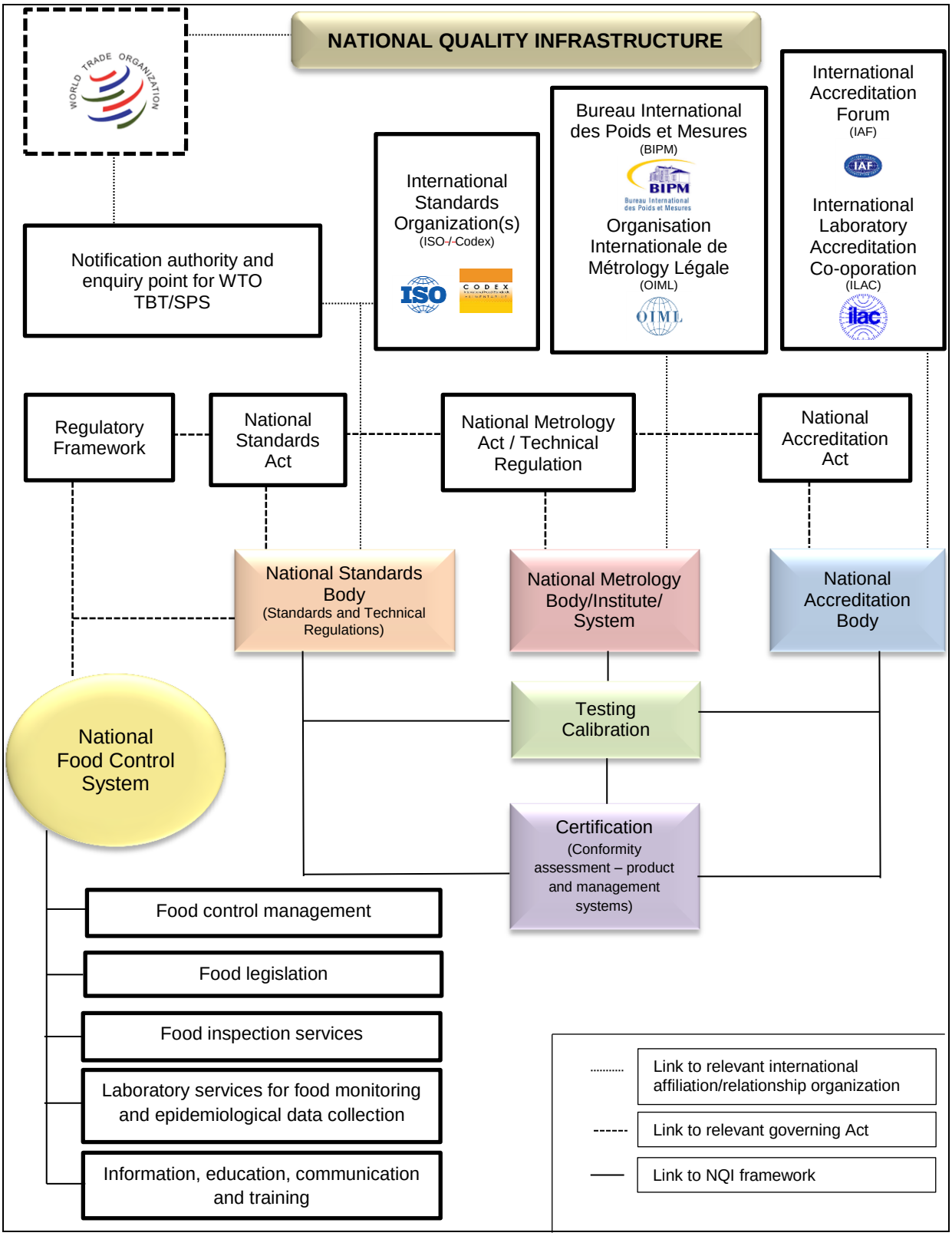


**Figure 1:** A proposed schematic representation of a NQI incorporating and integrating components of international affiliations, regulatory frameworks and associated national bodies

National Standards Body
(Standards and Technical Regulations)

### 2.3.1 Pillar I: A National Standards Body (NSB)

According to Sanetra and Marbán (2007) an NSB is normally governed by a country's National Standards Act and is mandated to set up and give access to standards.

National standards are developed by technical committees on a national level, reflecting the needs of the country, or they can be accessed through the NSB or adopted from other international standards bodies by the NSB and are then applied as adopted standards on a national level. It is important to note that the development of standards should be an open, transparent, impartial, stakeholder-driven and consensual process (Steyn, 2010). The methodology applied for the development and adoption of standards is based on international best practices, i.e. ISO/IEC Guide 59 (1994) and ISO/IEC Guide 21-1 (2005), and is generally the required methodology promulgated by the agreements under the WTO which were developed based on the Code of Good Practice for the Preparation, Adoption and Application of Standards noted in Annexure 3 of the WTO TBT Agreement (Steyn, 2010). Standards bodies may also participate as members of international standards or regional standards organizations and may therefore either adopt those standards as national standards or sell those standards in their country. Information on standards is also supplied to industry through the NSB.

Standards are broadly divided into three categories, i.e.

- Product standards, referring to the characteristics of a product relevant to its quality or safety;
- Process standards, referring to the conditions under which the product or service is to be produced, packaged or refined; and
- Management system standards, referring to the requirements to manage one's operations in order to create a framework to consistently achieve the desired output of the system in relation to the product or service (ISO, 2006; ITC, 2010).

Standards are generally applied from a voluntary basis, but in certain circumstances are made mandatory based on the importance and impact on the consumer and the environment. Mandatory standards can be referred to as compulsory standards or technical regulations. Access to standards, whether national or international, supports the producer of products and services to apply consistent processes to produce and measure its products and services that are of a national and/or international acceptable standard and therefore support customer satisfaction.

Standardization as the main objective of the NSB plays an integral role in the contribution to international trade based on the increasing globalization of markets. International standards, i.e. from ISO or the International Electrotechnical Commission (IEC), are becoming critical to trade and ensuring that a competitive field for exports exist as well as for the importing markets to ensure compliance with recognized levels of performance and safety (ISO, 2006). Standardization further contributes to the society in terms of its health, environment and promoting sustainability and good practices (ISO, 2006). Standardization improves economic efficiency and provides access to world markets, but only so if it is supported by reliable measurements and a demonstration that items conforms to requirements specified in standards (ISO/UNIDO, 2010).

The NSB will represent its country at ISO through an official technical committee mirroring the ISO technical committee. The membership can be as a full member with voting status, corresponding member with an observer status or as a subscriber member who just keeps up to date with ISO's work. The membership status allows for a certain level of participation in the development, selling and adoption of ISO standards in support of global standardization and harmonization.

The NSB is also appointed to be the national enquiry point in relation to the agreements under the WTO (Sanetra and Marbán, 2007; ITC, 2010).

National Metrology Body/Institute/ System

### 2.3.2 Pillar II: A National Metrology Body (NMB)

Metrology plays an important role in trade and even more so in international trade as it provides the technical means towards correct measurement of the harmonized

measurement system consisting of the international system of units of measurement referred to as the Système International (SI). An NMB is governed by the country's National Metrology Act and is the custodian of the national measurement standards in order for measuring equipment to be related to these SI standards.

Metrology includes a combination of work conducted by national measurement institutions and international treaties, for example the Metre Convention that allows the International Committee for Weights and Measures (CIPM) and the national measurement standards that are traceable internationally to the International Bureau of Weights and Measures (BIPM) to act on measurement standards for their ongoing accuracy, range and diversity (ISO, 2006). The BIPM is therefore responsible for the establishment and maintenance of reference standards which then include long-term stability, organizing and participating in international comparisons, carrying out calibrations and investigations towards the improvement of reference standards or measurement techniques. NMBs are encouraged to participate in international comparisons as part of their signed mutual recognition agreements noting the acceptance of member's calibration certificates, and therefore to demonstrate equivalence between national measurement standards and standards of other countries. Measurements, including calibration, can then on a national level be applied with confidence and are reliable in producing true results of production and service outputs (Steyn, 2010).

Metrology is commonly applied in three forms, i.e. scientific metrology which includes the development of primary measurement standards and methods, industrial metrology which includes the maintenance and control of industrial measurement equipment which comprises the calibration of instruments and its working measurement standards, and legal metrology which includes the verification of instruments used in commercial transactions in accordance with criteria defined by technical regulations (Sanetra and Marbán, 2007). Legal metrology is coordinated by the International Organization of Legal Metrology (OIML) where legal metrology specifications are produced and adopted by countries (ISO, 2006).

For developing countries, the establishment of the NMB is in general considered a priority in terms of the development of the NQI framework because metrology

provides the foundation for standardization, accreditation and conformity assessment as it facilitates measurement acceptance for exporting products, law enforcement measurements as well as support towards scientific results (Steyn, 2010).

National Accreditation Body

### 2.3.3 Pillar III: A National Accreditation Body (NAB)

An NAB is the overseer of technical competency of measurements in terms of testing and calibration laboratories as well as inspections and certifications of products and management systems applied in a country, also commonly referred to as conformity assessment services (Sanetra and Marbán, 2007).

According to the international standard for conformity assessment, accreditation is defined as the 'third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks' (ISO/IEC 17000, 2004).

Accreditation systems are based on international standards and guides and are linked with membership of the International Laboratory Accreditation Cooperation (ILAC) and/or the International Accreditation Forum (IAF) mutual recognition arrangements which facilitate the mutual recognition of conformity assessment certificates, inspections and reports between NABs. This therefore provides a more cost-effective assurance that a supplier of testing and calibration services (ILAC) and certification services (IAF) is competent in carrying out its work which then further implies, for example, that conformity assessment data and reports of exporting goods are willingly accepted in cross-border trade therefore reducing the duplication of testing and inspections during trade (ISO, 2006; Steyn, 2010).

Accreditation will therefore provide information to regulators and the industry to make informed decisions when selecting a laboratory, certification body (CB) or inspection body that is able to demonstrate their competence, impartiality and capabilities (ITC, 2010). This by itself helps to overcome technical barriers to trade and it support compliance with the requirements of the WTO TBT Agreement (ISO, 2006).

### 2.3.4 Regulatory framework

The Oxford English Dictionary (2012) defines ‘regulatory’ as ‘acting to regulate something’, whereas ‘regulate’ is defined as to ‘control something by means of rules’. The word ‘framework’ is defined by this dictionary as ‘a supporting or underlying structure’ and that is most probably why the word regulatory framework is used in the majority of the NQI based documents and institutions of the NQI. A term derived from this is sometimes referred to as technical regulations where, for example, the WTO TBT agreement defines a technical regulation as ‘a document which lays down product characteristics or their related processes and production methods, including administrative provisions, with which compliance is mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method’ (Sanetra and Marbán, 2007; Steyn, 2010).

In the case of safety, health, environment and consumer protection, rules have to be compulsory. A standard is a document that is exclusively used for voluntary application whereas a regulation, also commonly known as a technical regulation, is applied as a mandatory document. The development and therefore the enforcement of these mandatory documents are the responsibility of governmental bodies, i.e. ministries related to that aspect of what needs to be regulated (Sanetra and Marbán, 2007).

## 2.4 Conformity assessment

Conformity assessment, according to ISO, ‘plays a critical role in building confidence for sustainable development and trade’ (ISO, 2006). Conformity assessment, as defined by ISO/IEC 17000 (2004), is the ‘demonstration that specified requirements relating to a product, process, system, person or body are fulfilled’. ISO/IEC 17000 further explains that conformity assessment may include the activities of testing, inspection and certification as well as the accreditation of conformity assessment bodies (ISO/IEC 17000, 2004). Accreditation of these bodies is applied for the body to demonstrate its competency in carrying out the function and/or service provided (ISO/UNIDO, 2008).

Conformity assessment in short, therefore, is applied to ensure that a product or service delivers on its promises, i.e. quality, safety, economy, reliability, compatibility,

efficiency, effectiveness, etc. (ISO/UNIDO, 2010). It benefits the consumers through assisting them to select products or services that they can trust based on a declaration, certificate of conformity or certification marking attesting to the quality, safety or specific desirable characteristic of the products or services (ISO/UNIDO, 2010). Manufacturers and service providers will make sure that they meet their declared conformance, customer expectations and regulatory requirements (compulsory by Government) through the application of and the measurement against ISO, IEC, National or other relevant International Standards in order to meet state-of-the-art standards and to avoid costly product failures (ISO/UNIDO, 2010). Regulators on the other hand benefit from conformity assessment through means of inspection or measurement against enforced national health, safety and environmental legislation which supports public policy goals (ISO/UNIDO, 2010).

Conformity assessment through third-party certification against management system standards has over the last decade increased to be seen as the only norm whereby a manufacturer, producer or food handler is able to supply a food product to a consumer, mostly required through retail and customers feeding into the consumer market. Management system certification has now also been identified by governments as a means to ensure a consistent and safe delivery of a product or service and is increasingly forming part of their selection criteria for the supply of food products and related services (Hatanaka, Bain and Busch, 2005).

Conformity assessment is applied through testing which includes calibration and measurements and certification which includes management systems, product and personnel certifications (ISO/UNIDO, 2010). The assessment is conducted against a set standard, specification or code of conduct set by a recognized body, i.e. national or international standards, compulsory specifications, regulations, metrology standards, specified test methods or customer requirements. The assessments are carried out by laboratories, inspection and/or CBs and/or a combination of the three and may be applied as a voluntary or regulatory function. A mark, permit or certificate of conformity is then issued to indicate compliance with the standard and is therefore under the ‘supervision’ of a conformity assessment system. The mark, permit or certificate then specifies the scope, therefore the item, component, product, process or system to which the conformity assessment process has been conducted

in relation to the standard or in some cases parts of the standard applied (ISO/IEC Guide 23, 1982).

It is paramount for the people carrying out conformity assessment activities to be competent and is therefore seen as the underpinning requirement for the accreditation of the organization providing the assessment activity (ISO/UNIDO, 2010). Accreditation is defined by ISO/IEC 17000 (2004) as the 'third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific tasks'. It is therefore important to note that the principal objective of accreditation rests with the recognition of competencies towards specific tasks (ISO/UNIDO, 2010).

Conformity assessment processes are an integral part of a NQI provide harmonization of conformity assessment practices when applied to product and services as part of international trade, a major obstacle found in cross-border trade where exporters are faced with costly multiple testing and/or certifications (ISO/UNIDO, 2010). Conformity assessment processes should be transparent and non-discriminatory in order to obey the intention of the WTO TBT Agreement to prevent technical barriers to trade or to create unnecessary obstacles during international trade (ISO/UNIDO, 2010).

Third-party certification as part of to conformity assessment of management systems and therefore its particular relevance to this study is supplied to the market place through CBs. CBs may include governmental or private institutions which then in a way have a known claim to independence, objectivity, transparency, impartiality and an acceptable and verified level of competence. These claims are made based on the fact that a CB has no stake in the outcome of the assessment other than an independent view of the assessment results. These known claims are also verified through an accreditation process and this then allows for third-party certification to become a means of independent ensuring that the output of processes towards, for example, food is consistently safe (Hatanaka, Bain and Busch, 2005).

The CB applies standards for their conformity assessment functions and these standards could include a combination of National, International or Private

Standards. The selection of the standard to be certified against is based on the choice of the organization requesting certification and its choice is mostly influenced by its customer. In addition to the standard which will be certified to, the CB in its operations are obliged to implement International Standards towards management system certification and this forms the foundation of its operations and the accreditation of its operations. The ISO/IEC 17021 (2011) standard is the selected International Standard for accreditation of CB's certifying management systems and in specific cases is supported by scheme specific Standards, i.e. for food safety, ISO/TS 22003 being of relevance.


## 2.5 The role of a National Food Control System (NFCS)

Before looking into the role of an NFCS and its place within the NQI, the difference and in application between standards and technical regulations may need to be clarified. Steyn (2010) notes that the WTO TBT agreement defines a technical regulation as 'a document which lays down product characteristics or their related processes and production methods, including administrative provisions, with which compliance is mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.' A standard on the other hand is 'a document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products and their related processes or production methods with which compliance is not mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.' Technical regulations are therefore mandatory, are commonly referred to as legislation and are the responsibility of government. Products that do not comply with technical regulations may therefore be denied access to markets. Standards are voluntary and technical regulations may refer to standards and in particular international standards when, for example, product characteristics are described. There is therefore a synergy between technical regulations and standards and therefore a logical approach is to place an NFCS into the same framework as the NQI, especially when food safety is of concern and in fact should be so for every country.

According to CODEX (2013), the objective of an NFCS 'is to protect the health of consumers and ensure fair practices in the food trade'. Food control, according to the FAO/WHO is defined as 'a mandatory regulatory activity of enforcement by national or local authorities to provide consumers protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law' (FAO/WHO, 2003).

The establishment of an NFCS seemed to contain various principles and guidelines recommended by CODEX and the FAO and were also reiterated by the study conducted by Al-Busaidi and Jukes (2015) on the food control systems in Oman, for example:

| Codex principles | FAO guidelines |
|---|---|
| • Protection of consumers<br>• The whole food chain approach<br>• Transparency<br>• Roles and responsibilities<br>• Consistency and impartiality<br>• Risk-based, science-based and evidence-based decision-making<br>• Cooperation and coordination between multiple competent authorities<br>• Preventive measures<br>• Self-assessment and review procedures<br>• Recognition of other systems (including equivalence)<br>• Legal foundation<br>• Harmonization<br>• Resources | • Food control management<br>• Food legislation<br>• Food inspection<br>• Official food control laboratories<br>• Food safety and quality information, education<br>• Communication |

Source: CODEX, 2013; Shukla, Shankar and Singh, 2014; Al-Busaidi and Jukes, 2015

Annexure 2.1 includes further descriptions of the recommended CODEX principles towards the establishment of an NFCS. Al-Busaidi and Jukes (2015) go further by stressing that through a definition form the FAO noted as ‘a continuous process of planning, organizing, monitoring, coordinating and communicating, in an integrated way, a broad range of risk-based decisions and actions to ensure the safety and quality of domestically produced, imported and exported food for national consumers and export markets as appropriate’, attention should be placed on the management of food safety through risk analysis concepts published by CODEX, i.e. risk assessment, risk management and risk communication.

An NFCS should preferably be based on a country’s governmental or constitutional arrangements and institutions, national goals and objectives and should cover all food produced, processed and marketed in the country, including imported foodstuffs (FAO/WHO, 2003; CODEX, 2013; Al-Busaidi and Jukes, 2015). The design of the system should comprise the national legal framework, links with international and national standards including those relevant to food imports and exports. Figure 1 reflects the proposed place and therefore relevance for an NFCS within a NQI framework. The system should also give recognition to other food control systems, have knowledge of controls throughout the entire food chain, risk management, emergency and recall programmes, enforcement and compliance programmes, and have access to adequate laboratories, staff competence and training programmes. Resources to achieve its objectives, surveillance, investigation, evaluation and continual improvement programmes, stakeholder engagement programmes and international communication and harmonization plans should be made available as part of the country’s governmental arrangements for it to be fully functional (CODEX, 2013). The system should allow for access to information and data on food safety hazards and their risks based on scientific data as well as information on epidemiological data on food-borne disease in support of the establishment of effective food control programmes (CODEX, 2013). The framework of the system should be designed around the concept of continual improvement based on a continuous cycle of policy setting, system design, implementation, and monitoring and system review (CODEX, 2013).

The rapid globalization of the food trade has placed an increased potential towards food-borne disease. The WTO TBT and SPS agreements and member country's obligation to honour the agreements imply that countries should strengthen their food control management systems with the focus being on risk-based strategies (Al-Busaidi and Jukes, 2015). The incorporation of an NFCS into the NQI framework is therefore a sensible strategy that needs to be applied by governments in order to continuously and effectively ensure protection of consumers against food-based risks.

## 2.6 Capacity building

The term capacity building is used extensively by sponsorship programme owners assisting in aid towards the upliftment of economies, organizations, and groups or individuals. Capacity building definitions, meanings and interpretations have been stretched by these programme owners to include what they intend to do in terms of their own planned development of knowledge or specific programme output or more specific as 'the ability of people, institutions and societies to perform functions, solve problems, and set and achieve objectives' on a sustainable basis (DFID, 2008). This is also about 'building abilities, relationships and values that will enable economies, organizations, groups and individuals to improve their performance and achieve their development objectives' (UNEP, 2006).

No singular definition of 'capacity building' can be pinpointed. Law (2009) defines 'capacity' as 'the highest sustainable output from an operating system in units per given time' and where a 'system's overall capacity is determined by the capacity of its narrowest part, i.e. the bottleneck' which may then in terms of this study be interpreted as the pressure point, for example, in terms of resources of the organization delivering the intended output. The Oxford English Dictionary (2012) on the other hand defines 'capacity' as 'the maximum amount that something can contain or produce' which then reiterates the concept of a 'bottleneck' which may occur in producing a product or supplying a service in terms of trade. 'Building' can easily be defined, and as stated in the Oxford English Dictionary (2012), building is the construction of something by putting together parts or to use something as a basis for further development. Capacity building can therefore as a consolidated explanation mean that it is a continuous construction process where various parts of

abilities are strengthened to perform core functions, to solve problems, to define and achieve objectives and to understand and deal with development needs in order to achieve the highest sustainable output through the narrowest point of operation (UNESCO, 2006; Law, 2009; Oxford English Dictionary, 2012).

The building of capacity is mainly an internal process enhanced by the assistance of someone outside of the organization, i.e. by donors (UNESCO, 2006). Capacity building is mostly applied to existing capacities rather than starting from scratch (UNESCO, 2006). It is further described by the United Nations Environment Programme (UNEP) as initiating and sustaining a process of individual and organizational change (UNEP, 2006). Capacity building can be seen as a process which involves the complexity of learnings of individuals and the organization. Complexities involve people skills, knowledge, attitudes, social undertaking and to build a long-term culture within an organization through collective capabilities to achieve set organizational objectives, goals and achievement of results (DFID, 2008). This implies change towards individuals and the organization.

In the case of an individual, and therefore the human resource, a capacity building process is a process where an individual is equipped with the skills and understanding of accessing information through knowledge and training in order to perform effectively therefore also promoting job satisfaction and self-esteem (UNESCO, 2006).

Organizational capacity building processes involve the expansion of management structures, processes and procedures supporting the setting of legal or regulatory frameworks to enable organizations at all levels to enhance their capacities (UNESCO, 2006).

An essential aspect of capacity building is to assist the receiver, whether an individual or the organization, with coping with change and to, on an integrated and holistic approach, narrow the sectorial ways of thinking during the processes of problem-solving (UNESCO, 2006).

Capacity building is a long-term process which requires long-term commitment, and a commitment to change, and also requires a broad selection of measurements over the period of change (UNESCO, 2006). This therefore involves the consideration of both short- and long-term dimensions to the expected capacity building process in order to ensure a long-term successful output (DFID, 2008).

Capacity building towards sustainable development in developing countries underwritten by various donor organizations is applied through various programmes and is not applied as a single unit towards the development of a single organization or individual. Capacity building projects within a country can be aimed at agricultural development, rural development, disease and health support, basic education and higher education, government institutions, policy and legislative setting, standards organizations, engineering and development, small- and medium-sized enterprises, and social development programmes. It is the collective effort of donor organizations that support sustainable development of developing countries, many of which flow from the need to establish and sustain a NQI. Building human capacities and institutional capacities, although equally important, requires different strategies applied by different stakeholders (UNEP, 2006). Strategies which are offered through training, workshops, seminars, conferences as well as analytical and decision-making capacities are applied through individual and personal interfaces between the giver and the receiver which are required to sustain a constant process of change (UNEP, 2006).

## 2.7 Conclusion

The WTO is the centre of trade and trade negotiations, and through consensus voting from member countries supports the enforcement of negotiated multilateral trade rules. WTO member countries are obliged to develop and apply a NQI based on the framework of standardization, metrology and conformity assessment in order to aid trade and to honour the TBT and SPS agreements when trading in food. Barriers to trade are categorized as ‘tariff based’ or ‘non-tariff based’. Standards and technical regulations supported through the NQI framework are regarded as non-tariff based and are focused on the health and safety of humans, animals and plants in mainly the SPS agreement arena (Steyn, 2010; WTO, 2011).

Three quarters of the WTO member countries are developing countries (WTO, 2011). Developing countries which include Ethiopia, face challenges with the development and ongoing effective and viable application of a NQI framework. Challenges are based on the lack of financial, structural, human and knowledge resources (ISO, 2006). These challenges are further pressured by an era of trade globalization and where the application of 'best international practice' is an expectation by all parties involved in the trade of products and services through a modernized technical infrastructure and international recognition (Steyn, 2010; ISO/UNIDO, 2010).

During trade, countries should not discriminate between trading partners, whether they comprise imported goods or locally produced goods. Technical barriers to trade should only be allowed to feature to ensure the safety of humans, animals and plant life. Voices should be heard when barriers to trade have been instated and they unfairly interrupt trade. The WTO has therefore set up through their trading partners agreements on the principles of fair trade. These agreements should be applied in each member country to promote these principles and therefore to promote development. This placed an obligation on member countries to develop and apply a NQI based on the framework of standardization, metrology and conformity assessment.

Developing countries, including therefore Ethiopia, should apply the most practical and cost-effective means towards conformity assessment processes as part of the NQI so that it is not only viable in the required protection of its consumers, but also viable for the business operation that needs to sustain business through accessing local and international markets. The functionality of the NQI in support of conformity assessment, and in this particular study case third-party certification, will also impact positively on the effectiveness, efficiency, quality, reliability, compatibility and interoperability of the various role players within the NQI framework, and therefore overall promote trade, knowledge and technology transfer and good management practices (Steyn, 2010; ISO/UNIDO, 2010).

Governments take responsibility for setting up and carrying the financial burden for the national systems of standardization, metrology and accreditation services,

whereas commercial bodies can support the NQI with setting up of the supporting services needed to complete the NQI framework (ISO/UNIDO, 2010). This is not different from Ethiopia, and with a country stricken by many social responsibility needs, food and economic development pressures, the various role players may find it difficult to prioritize where financial aid should be applied to ensure the full development and effective application of services and activities required by the NQI framework. For developing countries, it is inevitable that the progression towards a successful NQI framework be based on sponsorship and financial aid in order to be aligned with 'best international practices' and to support the globalization of trade through imports and exports of products and services (ISO, 2006). Funding is inevitably provided with the support of technical expertise required to develop, implement and build capacity towards a successful NQI. Such capacity has a direct influence on trade competitiveness increasing or decreasing economic efficiency, and it is therefore important to support the successful deployment of the NQI framework (Steyn, 2010).

Capacity building can start once there is an acknowledgement of the existing capacity (UNESCO, 2006). A carefully planned assessment of the level of capacity and therefore the level of the need for capacity building should be carried out and evaluated before the capacity building project is initiated (ISO, 2006; UNEP, 2006; UNESCO, 2006). The most urgent challenges are identified through an initial needs assessment and the capacity building project should therefore be based on these needs (UNESCO, 2006).

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# CHAPTER 3

# A GAP ANALYSIS OF SHORTCOMINGS IN THE ETHIOPIAN CONFORMITY ASSESSMENT ENTERPRISE

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## 3.1 Introduction

The GIZ under the auspices of the NQI Project of the National Growth and Transformation Plan in Ethiopia required assistance in the field of conformity assessment towards the development of a food safety management system (FSMS) certification scheme that could become accredited once implemented. The overall objective of the NQI Project in Ethiopia was to build capacity towards the Ethiopia NQI thereby improving the competitiveness of manufacturing and service providing enterprises in line with international best practices. Transformation of the ECAE towards international best practices in terms of conformity assessment was one of the key result areas of the GIZ NQI capacity building project in Ethiopia. The ECAE provided conformity assessment services in the areas of product testing, inspections and certification. Accredited certification systems had to be delivered in order to build trust and competitiveness not only amongst local industry, but also internationally as a global trading partner.

A capacity building project was introduced at the ECAE under the management of the GIZ with the aim of supporting the ECAE with the development and implementation of a quality management system (QMS) to manage the FSMS certification scheme and which could be accredited against best international practices. The objectives of this capacity building project were to:

a. Establish documentation including a management system manual and relevant work procedures for the FSMS certification scheme based on gaps identified between the current accredited QMS certification scheme management system work procedures and the proposed FSMS certification scheme work procedures. Documentation had to be based on the recommended measures of ISO/TS 22003 in support of ISO/IEC 17021.
b. Assess the certification personnel qualifications, develop a competence matrix of the system certification team (for FSMS lead auditors, auditors, technical experts, and certifiers, and those conducting contract review, and internal audits), and recommend training and/or twinning arrangements based on the identified gaps.

c. Provide a two-day orientation training session on the established FSMS certification process and working documentation for stakeholders of the FSMS certification scheme, and
d. Select a food manufacturing facility, conduct an assessment as a consulting audit, and propose corrective actions to be taken in order to achieve a typical FSMS certification status.

## 3.2 Materials and methods

The standards and mandatory requirements applied to this part of the study included the current set of work procedures of the ECAE applied to an accredited QMS certification scheme and the mandatory international standards and supporting documents applied for establishing, implementing and maintaining an accredited food safety management system certification scheme. As a minimum, reference had to be made to ISO/IEC 17021 and ISO/TS 22003 as the foundation requirements to a food safety management system certification scheme. Further mandatory and voluntary requirements were information supplied by the IAF and the selected accreditation body in terms of their specific or additional requirements. Supporting information had to be included regarding what the scheme intends to certify against, which in this case referred to ISO 22000 (2005) and ISO/TS 22002-1 (2009).

The methodologies were initiated by conducting a gap analysis to identify the capacity building needs required to fulfil the objectives of the project. Interaction with the FSMS certification stakeholders took place through individual interface, training sessions and meetings where recommendations were put forward to deal with the required capacity building needs. The gap analysis and interaction methodologies executed were based on the application of the following five activities:

- Activity 1 (In addition to the objectives): A review of the organizational structure of the ECAE in context of the NQI framework in terms of standardization, regulation and conformity assessment and the organizational needs required to fulfilling the requirements of the mandatory international standards and supporting information.

This activity was conducted in addition to the objectives to assess the capacity of ECAE to conduct certification activities as an integral part of the NQI framework. The ECAE certification directorate was not a stand-alone certification business, as sometimes found within the certification arena. The ECAE certification business was incorporated into the overall standardization, regulation and conformity assessment services provided to Ethiopia. This meant that resources were shared by the various business activities of the organization and the various role players of a NQI. Shared resources were seen to possibly impact on the effective performance and operations of the certification directorate and therefore the need to establish if the organization can support the certification directorate's operational needs. Furthermore, the ECAE formed an integral part of the NQI in Ethiopia which led to the decision to assess the organizational structure in context of the NQI and the underlying overall objective of the NQI Project of the National Growth and Transformation Plan in Ethiopia.

The operational requirements for a certification business requiring accreditation in support of the overall functioning of the NQI remained the focus of this activity. The underpinning requirements for this activity were based on the requirements of the mandatory international standards and supporting information needed for the establishment and accreditation of a certifying business. Practical experience in the field of FSMS certification formed the background to this activity.

A typical organizational structure of a certification business in relation to a NQI is reflected in Figure 2 and indicates the interrelation between the three pillars of a NQI, the certification client, also sometimes referred to as the audit client in auditing terminology, its supporting services within a functional NQI and the place and structural design of the certification business, also referred to as the CB in general terminology. This review of the ECAE Certification Directorate was conducted against the NQI role players illustrated by Figure 2. (Synthesis based on author's professional experience)

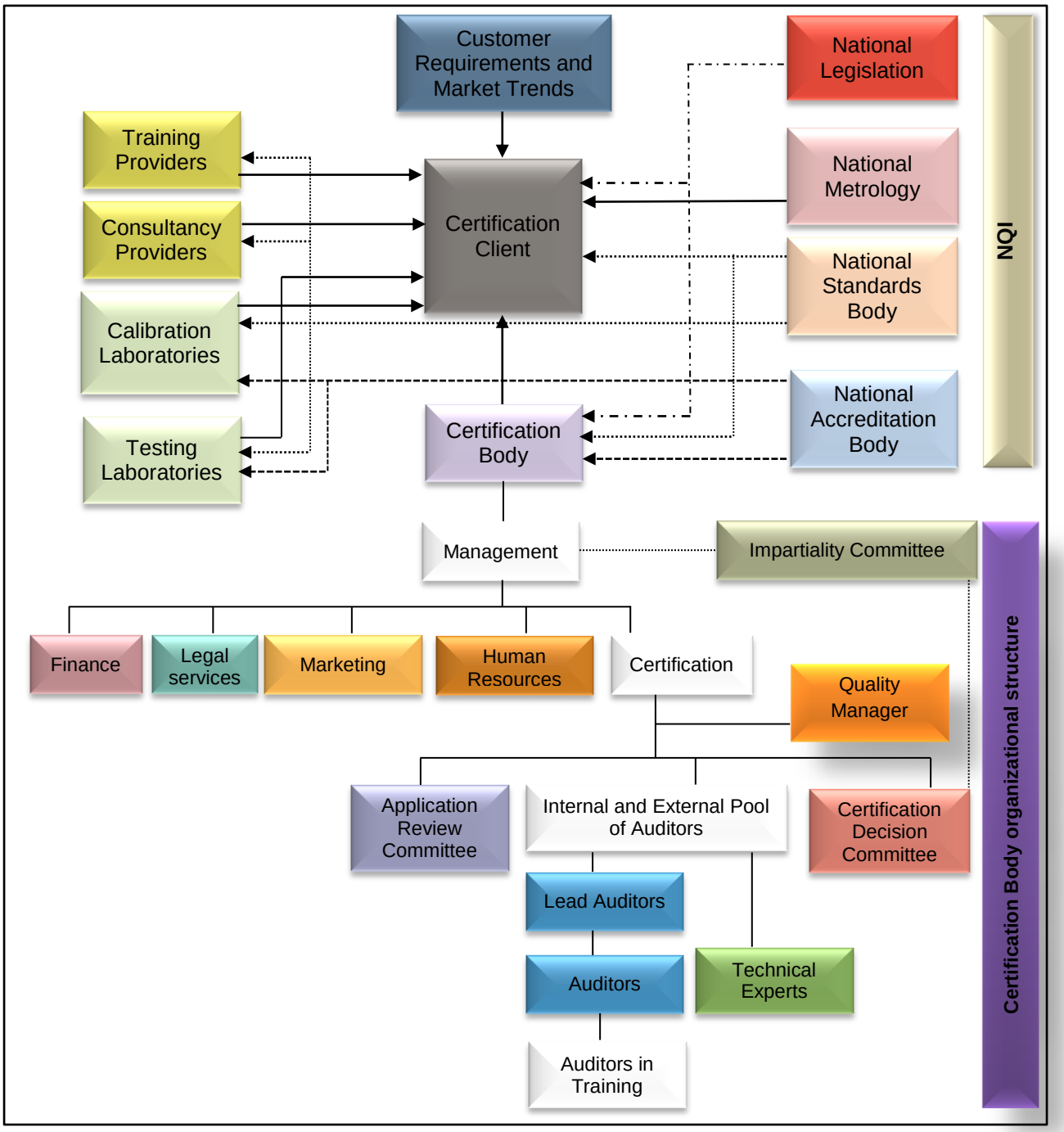


**Figure 2:** Illustration of the interaction between a NQI framework, certification client and CB, including a typical organizational structure of a CB

- Activity 2 (Objective a): A documentation review of ECAE management system certification QMS manual was conducted in accordance with the requirements of the mandatory international standards and supporting information. Annexures 3.1, 3.2 and 3.5 reflects the reference to the requirements applied to this documentation review part of the gap analysis.

A typical management system documentation framework for a business operating management system certification scheme is shown in Figure 3. This framework was used to review the QMS documentation of ECAE and supported the study project with the identification of gaps relevant to the documentation needs required to achieve the study project objectives. The thought process behind the development of the documentation synopsis as shown in Figure 3 was a result of the study of the mandatory requirements set for the establishment of a management system for a certification business needing to acquire accreditation as well as the experience in the implementation and application of accredited certification management systems over a range of management system certification schemes. (Figure 3 is the author's interpretation of the International Standards applied)

- Activity 3 (Objective b): A certification personnel review was conducted to establish the competency levels of the certification personnel during the certification process. Resource gaps towards fulfilling the requirements of the mandatory international standards and supporting information had to be identified and had to meet the competency level requirements required for an accredited status of the certification scheme.

Summarized personnel competency requirements are shown in Figure 4, and support the certification personnel categories shown in Figure 5. (Figures 4 and 5 is the author's interpretation of the International Standards applied) For the purpose of this part of the gap analysis, the certification personnel categories summarized in Figure 5 were selected and included in the review. Accreditation is based on the competency of personnel conducting the work which is an integral part of the service of the business provided to the customer. The competency criteria for these types of personnel include a combination of the noted criteria stipulated by Figures 4 and 5

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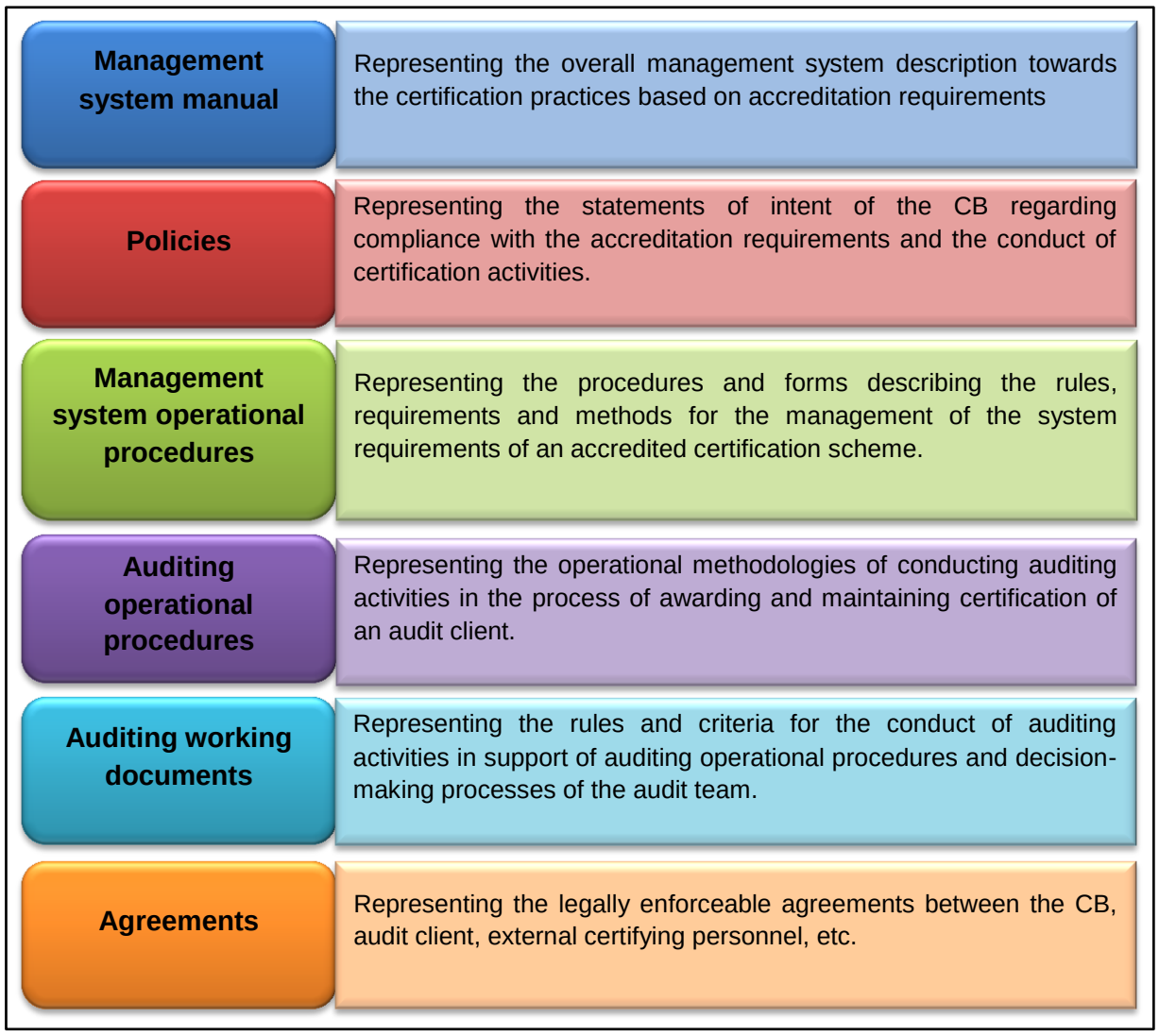


**Figure 3:** A synopsis of the documentation requirements of a business, typically referred to as a CB operating a management system certification scheme

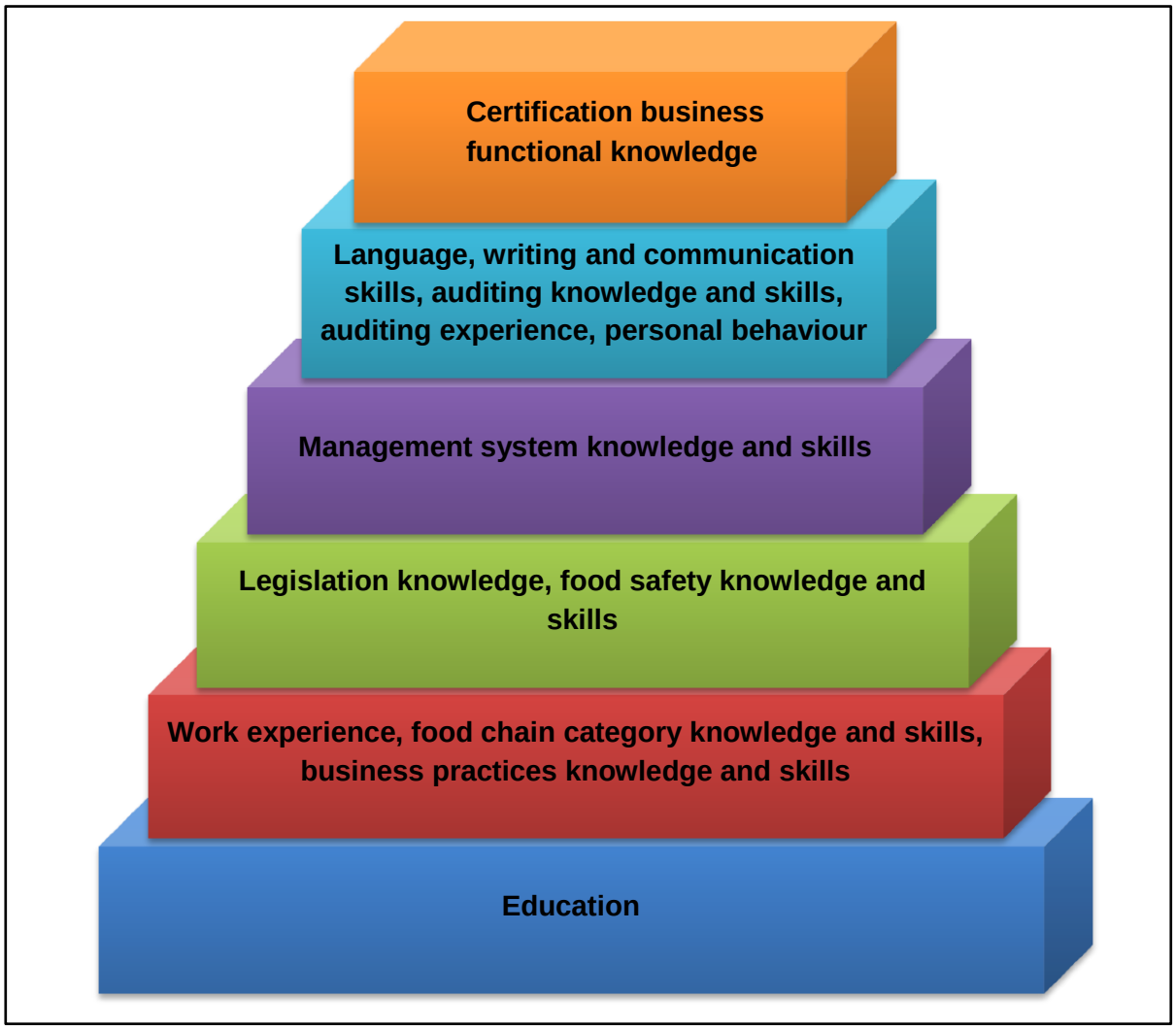


**Figure 4:** Illustration of certification personnel competency requirements summarized from the mandatory requirements applied to the study project

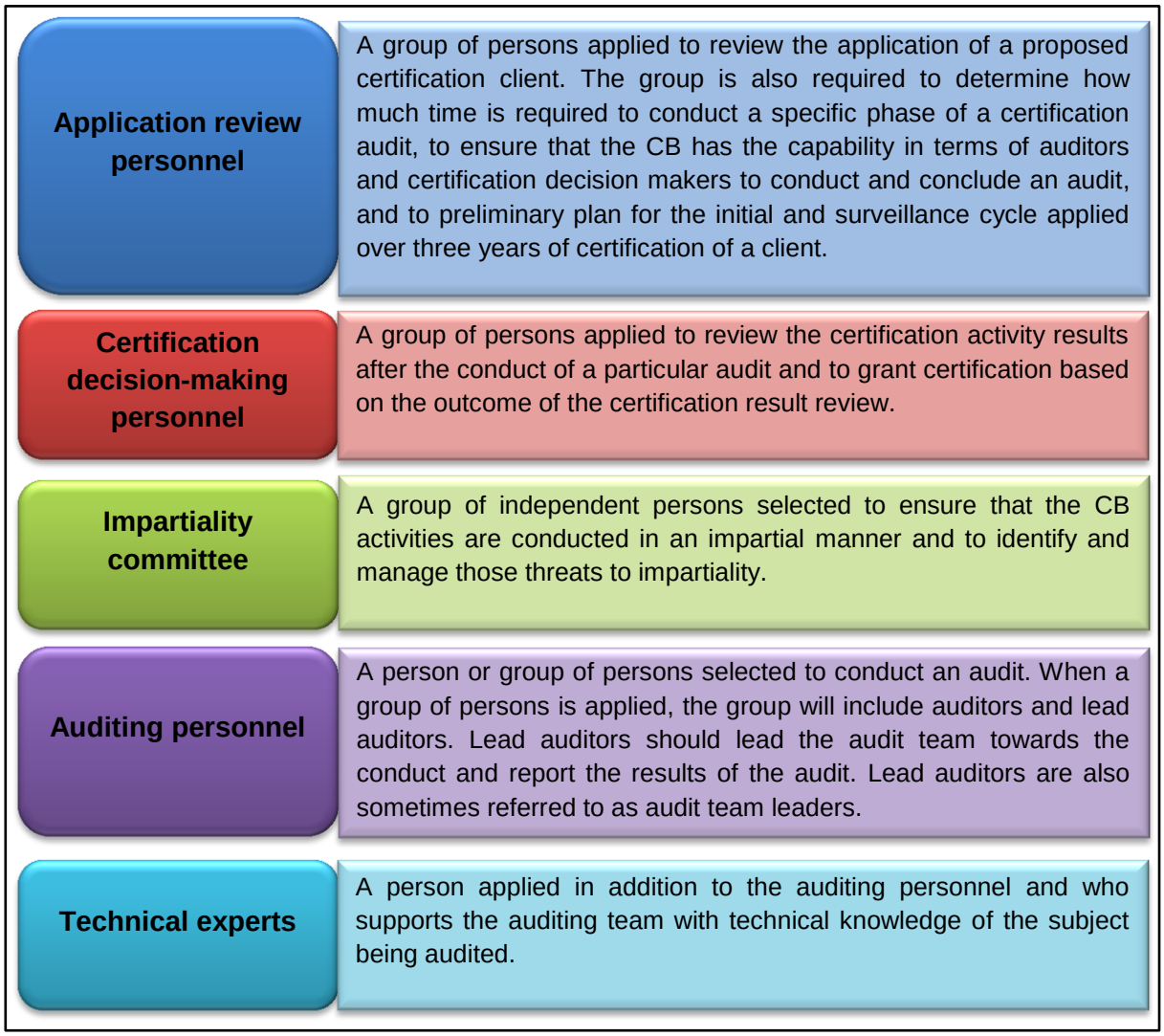


**Figure 5:** Summary of the certification personnel categories applied during a certification process

The international standards and best practices applied to certification of management systems require the certification personnel to be competent in the work they do. The competency of personnel, and therefore the accreditation of the certification business on the service provided, assists in building confidence, not only in the service but also as part of the output of the service, which in this particular case is a certificate indicating that a food producer is able to supply safe food based on an objective and independent assessment by a third party. This certificate is used to trade food products inside the borders of the country and also over the borders to other countries, therefore supporting international trade. Competency of personnel therefore plays an integral role in building confidence in the certification of management systems.

The review of the certification personnel focused on the education, scheme-specific training, working experience, auditor training and auditing experience of the pool of auditors and technical experts applied by ECAE as well as the management and administrative personnel applied towards the certification processes of the certification scheme. The focus of the review was further placed on the requirements for FSMS certification personnel and was based on the requirements of ISO/TS 22003 (2007) for certification personnel. ISO 19011 (2011) was used as a supporting document for the evaluation of auditors and technical experts.

As a minimum and in accordance with ISO/IEC 17021 (2011) the set criteria for auditing knowledge and skills of certification personnel for certification functions are reflected in Annexure 3.3.

In addition to the criteria set as noted in Annexure 3.3, ISO/TS 22003 (2007) stipulates requirements for the education, food safety training, audit training, work experience and audit experience of certification personnel involved in FSMS certification activities. Annexure 3.4 reflects these criteria.

FSMS certification personnel were further assessed against the food chain categories specified by ISO/TS 22003 (2007). These categories are reflected in Annexure 3.5. Certification personnel need to mirror the food chain categories in which the certification business intends to operate. The accreditation of the

certification business is based on the food chain categories of interest, and it is the competency of the personnel to assess and apply knowledge in that particular food category that will ensure the accreditation and therefore operations of the certification business in that particular category. Accreditation cannot be achieved without evidence of competency of the certification personnel in the particular food chain category of interest or operation.

Knowledge and skills of auditors are stipulated by ISO 19011 (2011) and are categorised into different aspects. Knowledge and skills are then further supported by specific requirements stated in the scheme specific requirement document, i.e. ISO/TS 22003 (2007). The knowledge and skills required for auditors are reflected in Annexure 3.6 and is supported by a solid foundation of the personal behaviours of an auditor in relation to the principles of auditing reflected by Annexure 3.7.

- Activity 4 (Objective c): A two-day orientation session was conducted on the proposed FSMS certification scheme processes and working documents derived from the study project.

- Activity 5 (Objective d): Food-manufacturing facilities were selected and assessed against the FSMS certification requirements, activities and processes derived from the study project and the related mandatory standards. The application of the developed FSMS documentation had to be demonstrated and explained to the certification personnel.

## 3.3 Results

### 3.3.1 Activity 1: Organizational structure review

The gap analysis was initiated by assessing the organizational structure of the Certification Directorate in context of the NQI in terms of support in its operation in fulfilling its duties as one of the important aspects of the NQI, i.e. conformity assessment. Figure 6, indicates the applicable aspects reviewed during this activity (The full illustration in context of the NQI, certification client and CB, is shown in figure 2). (Figure 6 - Synthesis based on author's professional experience)

National Legislation

#### 3.3.1.1 National legislation

The review of the availability and applicability of national legislation relevant to food safety and its certification activities within Ethiopia was complicated by the fact that the personnel interviewed were not yet familiar with any food safety legislation.

The library as a support function to the Certification Directorate was visited and interviews with personnel also revealed that they had no knowledge of legislation required for food safety.

The lack of knowledge of the applicable food safety legislation did therefore imply that the certification personnel had not yet determined the national legislation needs for food safety. Legislation forms an integral part of the application of ISO 22000 (2005), its certification process, and the specific food chain categories where the certification client needs guidance on the control of food safety hazards significant to a food product of that food chain category. The certification of a food facility without reference to and then application of legislation will impact negatively on the certification audit outcome as ISO 22000 (2005) requires compliance with 'statutory and regulatory' requirements. Collectively, food facilities that are unable to comply with the legislation requirements of ISO 22000 may overall stifle the successful application of the FSMS certification scheme. This means that most probably special certification arrangements would need to be made to overcome this obstacle until such time that Ethiopian food legislation has been established and implemented and

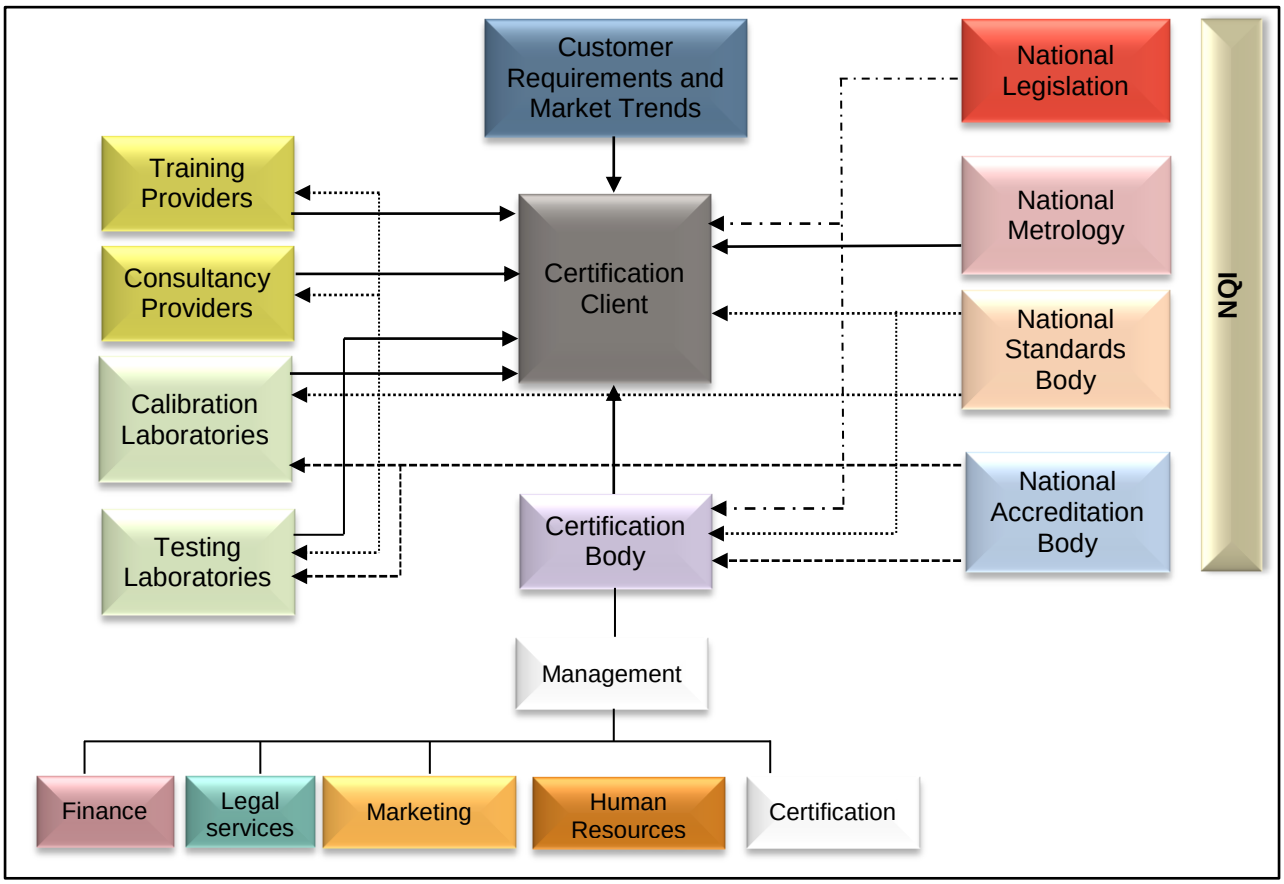


**Figure 6:** Illustration of the organizational structure review aspects relevant to activity 1

also to satisfy the accreditation body requirements in demonstrating that a food facility can fully comply with ISO 22000 (2005) and the concepts of food safety.

An Internet search was conducted during the review period to determine if any legislation relevant to food safety was available. The Internet search had further to be supported by telephone and email communications to various government departments as the ECAE had a direct communication line to the Government. During the process of searching for legislation information, it was found that the 'then' current legislation on Ethiopian Food was in a draft stage and had to be promulgated before it could be referred to in terms of food safety certification. A copy of the Federal Negarti Gazette dated 13 January 2010 was later located with the reference to Proclamation 661/2009 which provided for food, medicine and healthcare administration control. This Proclamation included the basic requirements of good manufacturing practices for food handling organizations.

The Food, Medicine and Health Care Administration and Control Authority of Ethiopia were later on identified as one of the possible role players in food safety legislation. One of its duties was to set standards for food safety and quality, safety, efficacy and the proper use of medicines, competence and practice of health professionals, hygiene and environmental health, competence of health and health-related institutions, and to ensure implementation and observation. Another role player, the Ministry of Industry, Trade and Agriculture was also identified as a possible role player.

Discussions with the ECAE personnel on legislation included the possibility of the Certification Directorate to participate in supporting the setting up of legislation as part of its role in honouring the WTO TBT and SPS agreements and therefore also ensuring the functionality of the NQI. The proposed legislation presented during the review period was able to support the food safety controls within Ethiopia but had to be assessed and possibly improved to also support the application of ISO 22000 and food safety hazard control in relation to food products from particular food chain categories. The discussion points and possible resolutions were put forward as a recommendation in the outcome of the gap analysis activity. The recommendation was noted under point D8 of Table 1.

National Standards Body

### 3.3.1.2 National Standards Body (NSB)

The Ethiopian Standards and Technology Agency was the supporting organization to the Certification Directorate within the ECAE in terms of training, consulting, technical assistance and provision of standards information and their sales. This agency operated as the NSB within Ethiopia.

The ISO 22000 (2005) standard was adopted from ISO by the NSB and was available as an Ethiopian Standard (ES) published as ES ISO 22000. The supporting standards to ISO 22000, i.e. the PRP related documents, national or international, were not available and therefore information on these supporting requirements were not known to the personnel interviewed. On request, the standards information services were able to trace the ISO 22000 supporting documents. These documents were then found and made available to the agency.

Under the rules of the operation of the agency, the non-Ethiopian standards are available for the public to view or read in the library and are also available for purchase. Photocopying of standards is not allowed under the copyright rules of ISO although ISO and other international NSB standards can be purchased. International standards are purchased in international currency depending on the country of origin, i.e. US dollars or UK pounds, something that would make the purchase of these standards unaffordable for the Ethiopian market owing to the currency pressures between a typical developing country and developed countries.

Access, based on the lack of knowledge of a standard and purchasing of standards, was identified as another obstacle facing the successful implementation of the FSMS certification scheme. The lack of access to or purchasing of standards by the industry will impact negatively on the implementation of these standards in a food facility and therefore the full compliance with ISO 22000 (2005). It would be very difficult for the food handler to implement for example PRPs based on ISO/TS 22002-1 without having a copy of the document on the premises. The certification personnel on the other hand would also not be able to include these standards in their certification criteria, documents and checklists implying that the full application

of ISO 22000 would not be able to be assessed and included in the certification of a food facility.

The library services also fell within this agency. The public was able to access national and international standards as well as book information on subjects such as microbiology or chemistry, relevant to food safety. A recommendation was made that information and documents relevant to ISO 22000 implementation be collected and placed in the library for access not only by the public, but also by the certification personnel.

Training and consulting services towards management systems were part of the agency. They supplied a support service to the industry in terms of management systems, their implementation and training. Their support was regarded as a positive resource for the industry and would have assisted in the positive outcome towards the success of the FSMS certification scheme.

During the search for relevant food safety standards in this analysis area a few Ethiopian National Standards on various food products, basic good manufacturing practice and HACCP activities, i.e. ES 588, ES 953, and ES 929, were identified. These ESs were available to the public for viewing and purchasing and could also be used by the certification personnel in their preparation for audits and inclusion in their audit working documents. The problem sometimes experienced with a combination of international and national standards on a subject, such as food safety, is the difficulty for the users of standards to decide which one to apply, and if they choose to apply both, how to integrate or supplement them in support of a FSMS that needs to meet international best practices.

From a certification point of view, the certification criteria would need to be clear on what is to be expected from a food facility to comply with standards, as the certification criteria are the underlying foundation for the audit criteria used on-site during an audit. The audit criteria will typically be a standard, e.g. ISO 22000 or ISO/TS 22002-1 or the integration of relevant National Standards. It was obvious that a process of education towards the application of national and international standards had to be considered, not only for the food industry, but also for the NSB

and the Certification Directorate. A recommendation was made to the NSB that they call for technical committees, whereof the certification personnel should be part of the development and/or adoption of standards relevant to the support of ISO 22000 (2005), i.e. PRP documents such as ISO/TS 22002-1 (2009) or equivalent standards such as SANS 10049 (2012). The application of standards within Ethiopia would be the prerogative of the NSB and the Government and was therefore discussed and left to the NSB to decide the way forward.

Some of the personnel working in the agency were part of HACCP and ISO 22000 training groups prior to this study project and were found to be knowledgeable on the requirements of FSMS certification. A recommendation was made to involve these personnel in the certification activities and also in the agency to support the building of knowledge through training, consulting and information. The personnel of the agency may also be applied by the Certification Division as part of the external pool of auditors and/or technical experts and could play a supporting role to the certification personnel in terms of their required resources. D1 of Table 1 supported these discussion points.

National Accreditation Body

#### 3.3.1.3 National Accreditation Body (NAB)

The NAB of Ethiopia was at the time of the analysis in the process of being established. This was done under the direction of a sponsored capacity building project. It was found that the majority of the accreditation functions applied in Ethiopia were supported by South Africa in terms of laboratories and also by Germany in terms of management system certification.

The application of cross-border accreditation support to countries in the process of developing their NQI is a common practice, however, it places a burden on the certification organization owing to the costs involved in using these bodies. The financial burdens on a CB such as the ECAE could impact negatively on the certification scheme and its long-term sustainability. These costs would certainly have an impact on the industry, an industry already targeted by obstacles in accessing global markets and the expense in reaching the expected trade requirements.


#### 3.3.1.4 Certification client

During interviews with the relevant certification personnel it became known that the FSMS certification scheme needs of food facilities in Ethiopia were not yet known. Various FSMS certification schemes were already available globally and could therefore also be regarded as relevant to the Ethiopian food industry, for example ISO 22000, Food Safety System Certification 22000 (FSSC 22000), BRC, and Global GAP. The basic knowledge and the status of certification schemes available and applied in Ethiopian were therefore very limited. This further implied that knowledge of the readiness of the Ethiopian food industry in applying ISO 22000 or any relevant FSMS certification standards or schemes was not available to the certification personnel interviewed. The personnel interviewed did therefore not know their market and the actual market needs for local and/or exporting food supply. Knowledge of the market needs for food safety certification was seen to be a crucial factor in the actual set-up of the FSMS certification scheme as the scheme determines the relevance of standards, training, consulting and overall relevance of the issued certification certificate needed to trade food in the global market place.

The results of visits to food facilities in the Addis Ababa area during the analysis period are described in activity 5 and revealed that in two out of the three cases, some basic aspects of food safety had not yet been accomplished by these facilities. Aspects such as basic hygiene practices in terms of hand washing, pest control, insufficient and inconsistent application of protective clothing, wearing of jewellery and religious clothing, lack of sanitation and hygiene practices when using toilets, infrastructure, working environment and scientific knowledge to apply HACCP effectively seemed to be lacking. Photographs of the visited facilities on page 127 and 128 shows some of the issues witnessed during the on-site visits. In the third case however, the sophistication of the facility towards food safety hazard control was surprising. Overall the lack of understanding of the application of science during the HACCP studies was evident and was revealed through interviews with the staff of the three facilities. The facility visits did reveal concerns about the readiness of the Ethiopian food industry to be certified in accordance with ISO 22000.

The ECAE was targeted specifically through this capacity building project under the auspices of the NQI Project to certify organizations against ISO 22000. At the time of this analysis, ISO 22000 as a certification scheme was already threatened by the introduction of the FSSC 22000 certification scheme, a scheme that was envisaged to overtake the market need preferences and influences in decisions towards food safety certification. Influences from consultants, other CBs, customer or supplier audits and customer requirements in general would depict the certification scheme of choice. Should the ECAE only be geared to certify against ISO 22000, the lack of additional certification schemes would force it out of the certification market and it would therefore not be able to supply the service and/or most probably needed by the Ethiopian food industry. The sustainability of the FSMS certification scheme will be placed under immense pressure rendering the value of the sponsored capacity building project unsuccessful.

The uncertainty of the readiness of the Ethiopian food industry for food safety certification therefore became a reality. A recommendation was made that a market review be conducted to determine the need for FSMS certification in Ethiopia and especially the type of scheme required. This was needed to gain knowledge of the market needs in support of the long-term sustainability of the FSMS certification scheme. The type of scheme to be applied in the industry would also assist the Certificate Directorate with the determination of the resources needed to be applied, the type of auditors required in the particular food chain category, market-related certification fees and possibilities of carrying over certification from another CB to the ECAE, including the possibility to convince a certification client to apply ISO 22000 instead of a national food safety standard or standards applied in other countries. All these aspects would impact on the details required for the development of the QMS of the FSMS certification scheme. Points C1 and D3 of Table 1 includes this recommendation.

Testing Laboratories

#### 3.3.1.5 Testing laboratories

A very basic laboratory review was conducted and included aspects of product testing with the focus on food safety within the Ethiopian food industry, the FSMS

certification and the ECAE or being a ‘one-stop’ service provider to the food industry in addition to the certification service. The microbiology, chemistry and food specific testing laboratories were operational within the ECAE compound at the time of the analysis and were therefore visited as part of the analysis.

This basic review revealed that these laboratories were also supported by this capacity building project under another phase of the overall programme. This meant that other experts were utilized for the capacity building of the laboratories and therefore included their own focus points in terms of testing of materials and products. These focus points did not in particular include the linking of testing towards food safety support and therefore indicated that, for example, testing for microorganisms included the basic hygiene organisms and not in particular pathogens, or for that matter, specific food safety hazards within food products. The focus of these experts was to build capacity towards the operations of the laboratories and their accreditation, an aspect needed as part of the NQI framework set-up.

Product testing in particular may not necessarily be a certification requirement, however, the knowledge of the presence and levels of food safety hazards within food products certainly is. The services provided by the laboratories of the ECAE therefore supported the food industry in controlling their food safety hazards to the acceptable levels established in support of consumer safety, an aspect also underlined by the WTO Agreements. This was seen to then be an indirect need for the support of FSMS certification.

Recommendations, noted under point D4 of Table 1, were made to the laboratories to assess the need of the food industry for the testing of food safety hazards, i.e. microbiological testing may need to provide for the most common pathogens tested for in the food industry such as *Escherichia coli*, *Escherichia coli H0157*, *Salmonella spp.*, *Listeria monocytogenes*, *Clostridium spp.*, *Bacilius spp.*, and *Campylobacter spp.*. Chemical and food chemistry testing may need to provide for the testing of, for example pesticide residues, aflatoxins, heavy metals, water potability, and allergens. The laboratory services may even be extended to the industry and the Government to, for example, include environmental and staff hygiene monitoring and training,

nutritional testing, shelf-life determination, packaging material integrity testing, and validation data collection on selected food safety hazards, which would support the ECAE being a ‘one-stop’ service provider to the food industry.

Training Providers

#### 3.3.1.6 Training providers

The Training and Technical Support Directorate was responsible for the provision of ISO 22000 (2005) training to the industry. This ISO 22000 training programme in support of the FSMS certification have already been established and have been presented to the industry on a few occasions. The training programme included a module on the understanding of ISO 22000 as well as a module on auditing practices. These modules were presented over five days for each module. The auditing course was shared with QMS auditing, which was problematic in terms of the different concepts between quality and food safety and then obviously the different focus points in their auditing. Auditing methodologies are very similar though, but it was recommended to rather have a unique auditing course for food safety. Most of the parts of the training material for the understanding course were found to be sufficient to support the industry in implementing an FSMS and ultimately achieving certification.

The HACCP aspects, however, needed more detail and relevance to the science behind HACCP and food processing in terms of the prevention, elimination or reduction of food safety hazards to levels that are acceptable for consumption. HACCP methods and examples given in the training material mostly reflected the basic ‘Codex’ concepts and not in particular the methodology required by ISO 22000 (2005), which are seen to be slightly different in comparison. The training material did not in particular refer to the available ESs or legislation. This indicated that not enough research may have been done on the relevance of legislation, supporting of national or international standards or other information relating to food safety and food safety hazard controls. What was interesting, however, was that the training material made reference to the South African standard for PRPs, SANS 10049 (2012) and could have originated from the fact that the original training on ISO 22000 was conducted by a South African project expert, and during a period when PRP standards were not yet known in Ethiopia. South African Standards are often used

by countries in Africa to support standards development and use, until such time that the countries have produced their own standards on a specific subject or aspect of the industry. The understanding course material had to certainly be reviewed and updated to include ISO 22000 specific HACCP methodologies and then reference to the Ethiopian related legislation and relevant national and international standards.

#### 3.3.1.7 Certification management

Certification

The management of the Certification Directorate was established to include a certification director, quality manager, team leader and a pool of auditors and technical experts, as illustrated by Figure 7.

The Directorate was managed by the certification director and included three types of conformity assessment activities, i.e. product certification, system certification and personnel certification. These conformity assessment activities were based on each of their own international standards and guidelines with each then being unique in methodology, activities and specific field of focus and therefore each having their own QMS. The product and system certification activities were found to be established and active in carrying out their respective activities. The personnel certification activities were found to be less active and in a way were still to be completed in order to reach the full potential.

A quality manager was available to the directorate and was responsible to ensure compliance with the QMS requirements of the various conformity assessment activities. For system certification in particular, the ongoing compliance with the ISO/IEC 17021 was paramount, especially owing to its already accredited status. The ECAE in terms of the overall organization had also employed a quality manager who was mainly responsible for the QMS activities of the organization as a whole. Interaction between the organizational and Certification Directorate quality managers was not very interactive and it was recommended to initiate better communication between the two for the purpose of following, for example corporate structures, formats, and policies in terms of the overall operations of the organizational QMS.

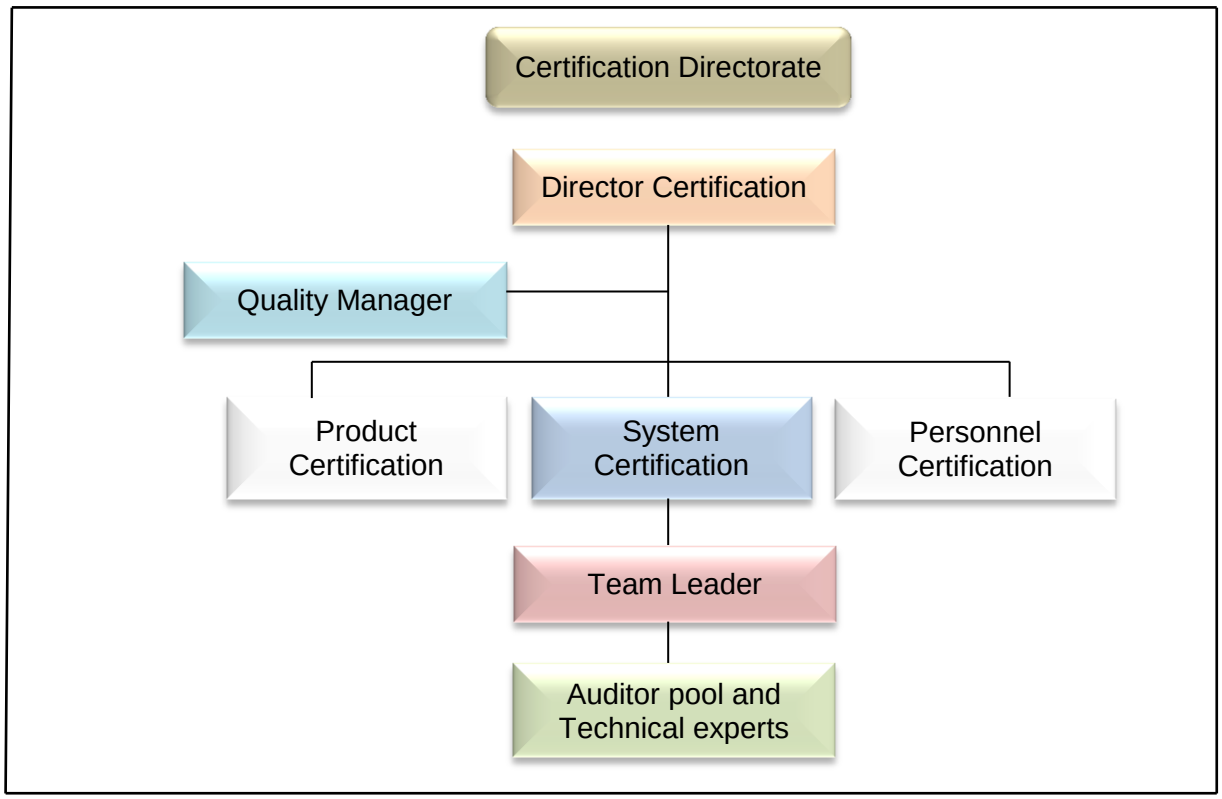


**Figure 7:** Illustration of the management structure of the ECAE Certification Directorate

The Certification Directorate quality manager remained solely responsible for the ongoing adherence to the certification QMS and related activities within the Directorate.

The day-to-day management of operational activities within the system certification area was carried out by the team leader. He was also responsible for the technical functions of the area which included the coordination of audits and nomination of auditors within the scope of accreditation. The QMS accreditation, which was in place, applied to the certification of QMSs based on ISO 9001 (2008). The ISO 22000 requirements had to be incorporated into this QMS. The team leader remained responsible for this activity.

An auditor pool and pool of technical experts were already active and they reported to the team leader. These pools were established with the focus to support the ISO 9001 certification activities. The details of their roles, functionalities and possible competencies in relation to ISO 22000 certification are reported on in the activity 3 part of this study report.

In general, the management structure of the Certification Directorate was typical of a CB that has achieved its accreditation. This structure was considered suitable to support the sustainability of the overall certification management activities. The analysis of the certification management activities also revealed that the certification director had a plant science background and was able to be utilized during the FSMS certification activities. The Certification Directorate quality manager had a biology background, which also made him suitable to be utilized for these activities. The team leader on the other hand had a chemistry background which would only allow him to be utilized for a small part of the FSMS certification activities. The team leader was an auditor, registered with the International Register of Certified Auditors (IRCA), which supported the concept of application of best international practices by the Certification Directorate in terms of certification processes.

### 3.3.1.8 Certification process

A major aspect of the success of the FSMS certification scheme is the application of an effective certification process. ISO/IEC 17021, as part of the certification requirements, recommends a certification process that consists of a logical sequence of activities. This recommended certification process is illustrated by Figure 8 and was used to review the certification process.

The certification process active in the Certification Directorate was based on the requirements of the 2006 version of ISO/IEC 17021 and was applied by the certification personnel to form the basis of the QMS certification scheme. The certification process for the FSMS certification scheme which was also to be based on the requirements set out in ISO/IEC 17201, however, had to be supplemented by specific requirements for food safety certification given in ISO/TS 22003 (2007).

The ISO/IEC 17021 standard was subsequently updated from the 2006 to the 2011 version which was then used for the review of the certification process. ISO/TS 22003 (2007) and the relevant IAF mandatory, guidance and information documents were also used to review the certification process in support of ISO/IEC 17021. Annexures 3.1 and 3.2 reflect summaries of the requirements used for this review.

The review revealed that not all the updated requirements of the 2011 version of ISO/IEC 17021 had been considered and incorporated into the QMS of the Directorate. A positive point was that a large part of the 2011 version was the same as the 2006 version which implied that a large part had been complied with. The 2011 version included additional requirements relating to auditors and auditing practices, similarly reflected by ISO 19011 (2011) which then meant their competency criteria. The accreditation of a QMS for certification focuses a great deal on the competency of the auditors and this therefore mean that certification personnel had to be reassessed in order to ensure compliance with the new ISO/IEC 17021 (2011) requirements. ISO/TS 22003 (2007) then went further to specify particular requirements for the FSMS certification personnel in terms of their education, food safety training, audit training, work experience, audit experience and competencies. This placed more pressure on the certification personnel in reaching

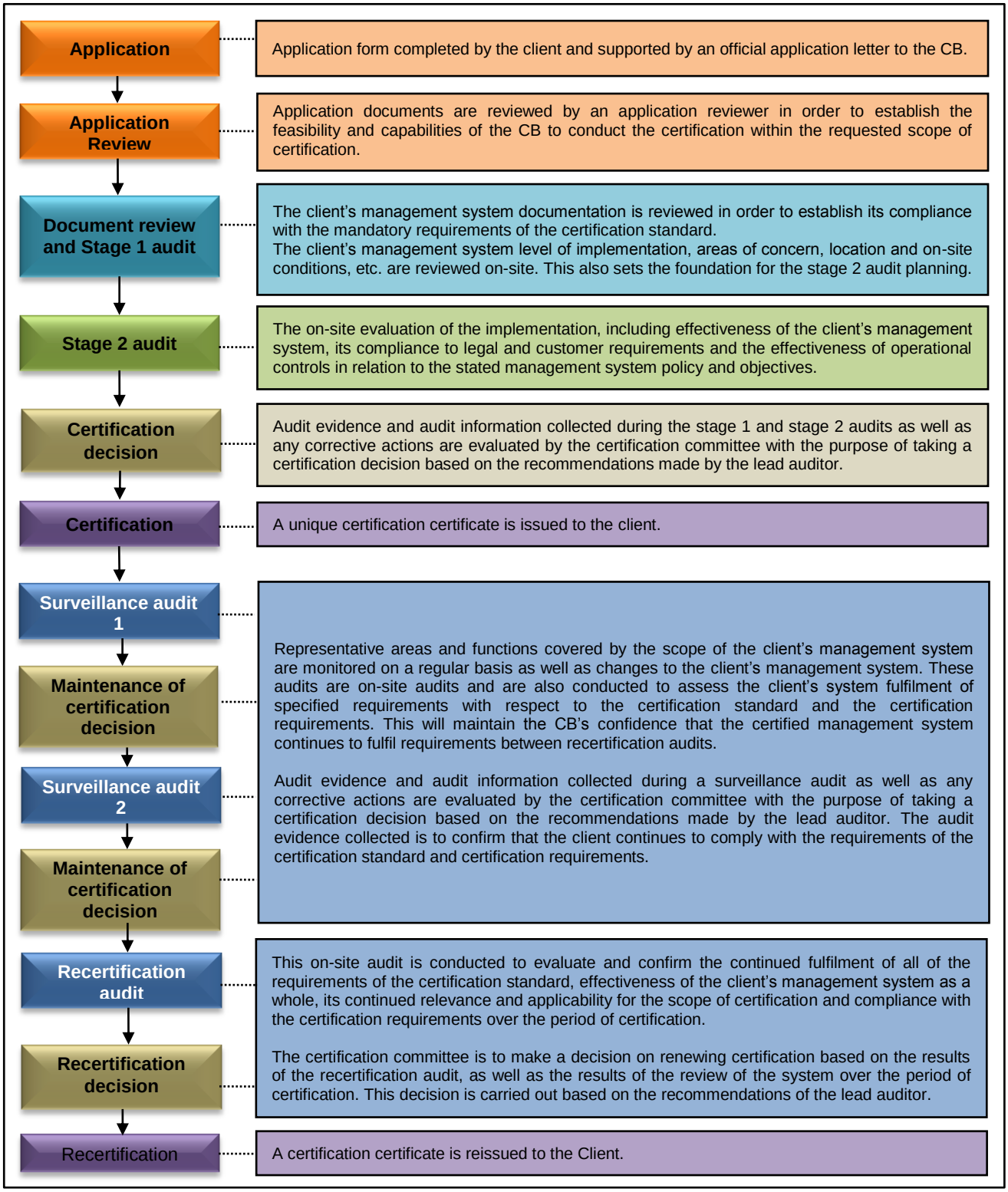


**Figure 8:** A proposed schematic diagram of a certification process summarized from ISO/IEC 17021 (2011)

the competency requirements for the FSMS certification scheme. These new and additional competency requirements had not been dealt with by the Certification Directorate.

In review of the certification process it was found that food safety specific technical working documents required for food safety specific certification still had to be developed. These specific technical documents included for example audit plans, audit checklists, audit reports, and certification certificates. The QMS certification scheme documents and certification process was found to be suitable to be used as a foundation to develop the FSMS certification specific technical documents and certification processes. Activities as part of the capacity building project were used to develop and correct these documents and processes and the remaining work that had to be completed by the certification personnel was noted under points C3 to C11 and B1 to B4 of Table 1. The challenge remained the compliance of competencies of the certification personnel specified by ISO/TS 22003 (2007).

#### 3.3.1.9 Human resources


Human resources were a shared function for various directorates within the ECAE and therefore also provided a service to the Certification Directorate.

When there was a need to employ a new person within a specific area, i.e. the Certification Directorate, the personnel requiring the new person had to set up the selection criteria for the new person and the roles and activities he/she is to fulfil. These criteria were then communicated to the human resources department. The head of human resources would then, based on these criteria, write up an advertisement for the position. The position would first be advertised internally, and then if applications or assessment of applications were unsuccessful, it would be advertised externally. The Certification Directorate in this case remained overall responsible to ensure that the correct person is selected, interviewed and then appointed. Any additional needs for the development of skills or knowledge of the new appointee were managed by human resources and would have had to be conducted based on a request from the Certification Directorate where again they were responsible for stating the required skills or knowledge to be gained.

The ECAE as a scientific-based institution, employed personnel qualified in the fields of plant science, biology, animal science and engineering. This was a positive point and was a good basis for the selection of food safety relevant certification personnel. What was found, however, was that the specific requirements for certification personnel were not known to the human resources personnel. They had very limited knowledge of what was required to meet the necessary competency requirements of the various certification personnel types noted in the ISO/IEC 17021 (2011) and ISO/TS 22003 (2007) standards. What was also interesting to note, was that the human resources area was not in a sense allowed to take control of the development of knowledge and skills for certification personnel, although generally that would be the case in terms of the functions of a human resources department or area. The certification personnel took charge of the development of skills and knowledge and the reasons behind that were based on the accredited status of the Directorate.

#### 3.3.1.10 Marketing

Marketing

The Government of Ethiopia identified the food product priority categories where certification of food facilities had to be conducted. These categories, noted in accordance with the food chain categories reflected in Annexure 3.5, therefore included the following:

a. Category C: Processing of meat, poultry, eggs, dairy and fish products.
b. Category E: Processing of canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt.
c. Category G: Catering in terms of hotels and restaurants.
d. Category M: Packaging material manufacturing.

The food chain categories and therefore most likely the food facilities within these categories were then seen as being the target market for the ECAE for its proposed accredited FSMS certification scheme. What was, however, revealed during the discussions with the marketing personnel was that they did not know about the various FSMS certification schemes and did not know what type of scheme would be of preference to the market.

Although the Government indicated its priorities for FSMS certification, a comparative analysis between the Government expectation and the actual market needs for FSMS certification, in particular the scheme of preference, and therefore supplying the local and/or exporting market of food products based on certified facilities was recommended. The market needs and therefore the preference to a certification scheme are influenced by the type of food facility, i.e. a multinational food producer, individually owned, rural, small or medium enterprise, as well as the customer's requirements. Multinational food produce, for example, may require FSMS certification in terms of the scheme type in line with its corporate strategies and requirements leading to the facility to abide by this decision. On the other hand, the customer may require a specific certification, i.e. FSSC 22000 or BRC or International Featured Standards (IFS), which then implies that the food facility should adhere to the customer's requirements to supply the food product. Neither of these scenarios aligned with Government priorities and expectations for FSMS certification, which were for ISO 22000 certification. This scenario puts pressure on the CB such as the ECAE as it may not yet be able to supply the particular certification service or preferred certification scheme required by the market.

Food exports, whether at border post inspection or from the customer, are known to be burdened by the requirement to supply evidence of compliance with standards, either through product testing against a standard or through accredited management system certification against a standard or scheme. These are all standards or schemes of preference which are often not determined by the food facility. The determination of the market need in terms of the certification scheme preference would impact certification directly as the scheme type and standards applied determine the type of competencies required for the certification personnel and the certification activities. The availability of competent certification personnel for the preferred certification scheme and the food chain categories that are to be certified will influence the type of accreditation required, i.e. if it was to be FSSC 22000, the accreditation body and the CB are influenced as they both need to be registered with this particular scheme owner. It therefore became evident during this analysis that the need to determine the actual market preference versus the Government expectation for FSMS certification had to be determined and in actual fact had to be

conducted prior to the initiation of this sponsored capacity building programme in order for the ECAE and therefore Ethiopia as a whole to benefit from this intervention ensuring sustainability of the FSMS certification activities within the country.

What was also not known was the status of current FSMS certified facilities in Ethiopia, the type of facilities, type of schemes and by whom the certification was issued and if it was issued through accredited CBs. the ECAE had to enter the market. This could mean that entrance to the market can be simplified by taking over certification from already certified facilities and/or the possibility for using such facilities for 'practicing' FSMS certification would give the ECAE access to the market as well as exposing the certification personnel to certified FSMSs. It was, however, important to focus on looking into accredited certification. This will ease the taking over of a certification, in contrast with non-accredited certification, where the certification processes are as complex and lengthy as an initial certification. Knowledge of the status of the market in terms of FSMS certification would also then influence the type and level of certification processes and procedures to be developed, including the development of a specific marketing strategy.

A certification certificate unique to the FSMS scheme also had to be developed, including additional tokens of recognition such as a flag, beacon of achievement or stationery. During the discussions with the marketing personnel on marketing items for certification and then by making use of the QMS certification scheme in terms of certificates and gifts as an example it was noted that the certificate design for the QMS certification scheme was seen to be unauthentic. This places a risk on the certification schemes in that the certificates may be easily falsified. Looking forward, the authenticity of certificates had to be investigated as the Certification Directorate was in the process to extend its certification services to environmental management systems and occupational health and safety management systems, therefore the need to ensure that certificate designs and marketing items had to be planned carefully before a problem such as the falsification of certificates and false claims of certification occurs. Although not reviewed, the authenticity of certificates of the other conformity assessment activities was also questioned and it was recommended in point C3 of Table 1 to investigate this issue further.

The analysis further revealed that the marketing of the proposed FSMS certification scheme for Ethiopia by the ECAE had not yet been planned or any marketing activity conducted. The marketing material and marketing means had to be established and it was recommended to consider marketing the FSMS certification scheme in the full context of food safety related services of the organization, i.e. food and microbiological testing, calibration, library services, standards, training and consulting and the certification of an FSMS, for now, based on ISO 22000 (2005). The concept of the 'one-stop' service organization for the food industry seemed to be an attraction point that would have not only supported the growth of system certification, but also the services relevant to food safety within the ECAE.

The marketing department was a shared function for various Directorates within the ECAE. Recommendations were made towards on overall market analysis and therefore needs determination of services required by the Ethiopian food industry. The various services, i.e. product testing, hygiene monitoring, food and food safety standards, product certification and management system training could all play a role in gaining market access to the FSMS certification arena. These recommendations were included in point D3 of Table 1.

#### 3.3.1.11 Legal services

Legal services

The focus of the visit to the legal services department was only to establish its assistance towards certification activities. Legal agreements for the conduct of certification as well as the use of external auditors and technical experts are requirements of ISO/IEC 17021. The agreements that were in place based on the QMS certification scheme were found to be incomplete in terms of all the requirements of ISO/IEC 17021 and now also the additional requirements of ISO/TS 22003. These legal documents were revised as part of the capacity building project and it was recommended in point D7 of Table 1 to put it forward to the legal services department for their assessment and approval to ensure it falls within the Ethiopian legal terms and framework of proceedings.

Finance

#### 3.3.1.12 Finance

The financial department, similar to the legal services department, had a role to play in the Certification Directorates operations other than management of general financial activities of the Directorate. Liability insurance for certification activities was already provided for based on the requirements of ISO/IEC 17021 and the QMS certification scheme. A financial and liability risk assessment for the FSMS certification scheme had, however, not yet been conducted and that implied that the liability insurance that was in place might not be suitable to cover both the QMS and FSMS certification schemes. Additional liability insurance had to be required to provide additional liability cover for the FSMS certification scheme in particular.

The sustainability of the Certification Directorate would further depend on the accuracy of the financial risk assessment and therefore the determination of how the Certification Directorate aims to generate income and remains financially independent form the ECAE organization. Financial processes in a certification related market had to be considered to establish a feasible and relevant financial strategy. The result of this risk assessment and financial strategy was also going to impact on the impartiality evidence that is required to support the impartial means of conducting certification activities. It was therefore regarded as a crucial aspect to not only ensure sustainability of the financial independence of the Certification Directorate but also ensure maintaining its accredited status towards certification. Recommendations were put forward in point D6 of Table 1 to deal with this aspect of the QMS of the Certification Directorate.

### 3.3.2 Activity 2: Documentation review

The documentation review included a two-phase approach. The first phase was conducted at the home office of the expert and was carried out for preparation for the on-site review and its related activities. The second phase was conducted on-site where interaction with the certification personnel could take place regarding the documentation and its actual application.

A fully developed and accredited management system based on the requirements of the 2006 version of ISO/IEC 17021 was presented for the documentation review.

The management system was drawn up with the assistance of a consultant over two years before this study project for the management of the QMS certification scheme and its accreditation. The QMS certification scheme was to be applied to organizations that required ISO 9001 certification.

The QMS of the Directorate was in a phase of being upgraded to the 2011 version of ISO/IEC 17021 when the review took place. This is not only a common practice by organizations applying these international standards but also required by the IAF and related accreditation body for the QMS and certification practices to reflect the newest version of the accreditation requirements. The benchmark for the documentation review was therefore based on the 2011 version of ISO/IEC 17021 rather than the 2006 version on which the QMS was based. ISO/TS 22003 was to be added to the management system for the purpose of establishing the additional required aspects of the management system in order to certify food handling organizations against ISO 22000. This scheme was referred to as the FSMS certification scheme.

The documentation review largely revealed that the QMS documentation had not yet incorporated all the updated and changed requirements of the 2011 version of ISO/IEC 17021. The writers of the QMS documentation found it difficult to interpret and therefore incorporate the new requirements into an already developed and accredited management system. Updates and changes to the standard also meant updates and changes to some of the operational functions of certain certification activities. The application of ISO/TS 22003 was actually limited to a few technical auditing documents and focused on the specific competency requirements of the certification personnel relevant to the FSMS certification scheme, which as such added to the complications of incorporating these requirements into the established documentation system and also into the already established certification activities. Training courses on the interpretation and application of these international standards used by the CB for the development of its QMS requirements and therefore its certification activities are generally not conducted, and the onus is on the users of these standards to apply the documents based on their own interpretation and application within their certification business based on their certification experience.

The QMS design in the study area revealed three levels of documents. The design is illustrated in Figure 9.

This design was reviewed in context of the certification activities and the application of the levels of documents in relation to the noted benchmark requirements. The review then revealed that, based on the functionality of the levels of documents, an additional level is required where criteria documents can be placed as they were seen to be unique in their own sense. The need for criteria documents specifying decision-making criteria that had to be applied in the auditing and certification decision processes were recommended and accepted. Corrections towards the levels of documentation were then put forward as a recommendation. Additional separation of documents required for specific purposes, i.e. legal agreements or policies was also recommended, however, it not accepted. The levels of documentation applied to the certification activities then included four levels.

Documents submitted for the phase one review included 34 documents. These documents were selected based on the decision of the team leader of the Certification Directorate for what was felt needed to be reviewed. The review results of these documents led to discussions and correction of documents during phase two of the review, where seven documents were discussed but not corrected and 27 documents were corrected after discussions. An additional 14 documents were identified during phase two of the review as being relevant to the overall review process and were therefore included in the collection of reviewed documents. The overall review results identified documentation gaps within the QMS based on the review requirements which then led to the development of 11 new documents during phase two of the documentation review.

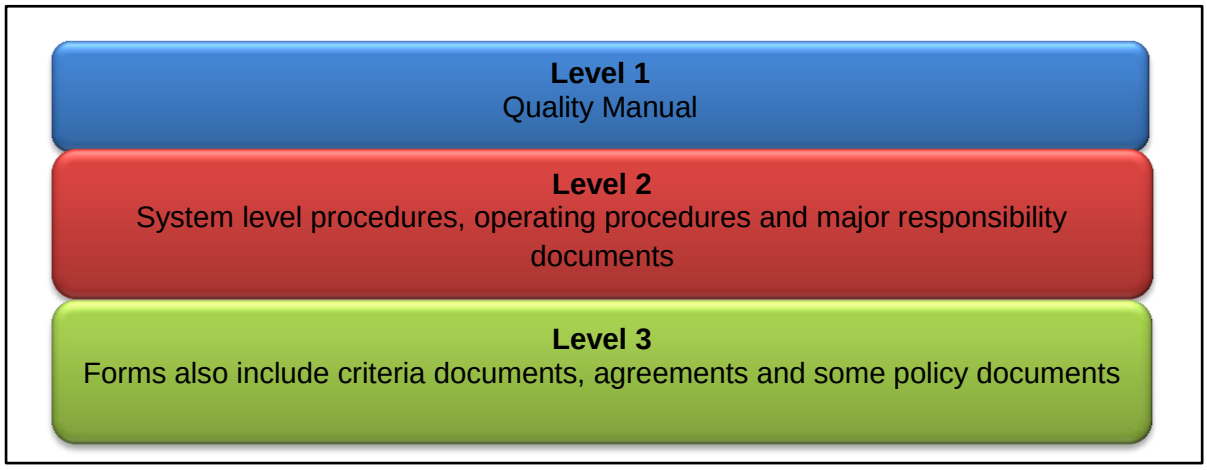


**Figure 9:** Schematic illustration of the levels of documents presented by the QMS design

The identification of documents within the QMS as indicated by the illustration in Figure 10 for controlling documentation revealed a unique numbering system, which is common practice in developing management system documentation. In this case, the first two digits identified the type of document, i.e. a procedure or form. The next two digits indicated 'CD' which meant the 'Certification Directorate' and then a number '1' or '2' number indicating '1' to be documents mainly used internally for internal certification operations and the '2' indicating documents to be used by certification personnel during a certification activity at the certification client's site. The numbering system did, however, not differentiate between the general Directorate operational QMS, QMS certification scheme and/or FSMS certification scheme unique documents. This observation was made based on the foreseen obstacles in the management of documentation of the QMS because of the incorporation of various certification schemes and therefore the practical and functional application of documents by users of the QMS. An additional coding for the identification of documents, i.e. a 'Q' prefix for the QMS scheme specific documents and an 'FS' prefix for FSMS scheme specific documents, was recommended. This recommendation was placed under consideration and a final decision on its implementation was to be taken later on.

Documentation reviewed made collectively reference to the term 'QMS certification'. This was seen to be in order for the accredited status of the QMS in relation to QMS certification, however, with the incorporation of the FSMS certification scheme activities into the QMS, consideration to the reference to more than one certification scheme within the QMS had not yet been considered. The reference to the application of documentation within the QMS was further on also confusing as there was also reference made to the internal documentation as 'quality management system certification'. It was recommended to apply a generic term when referring to management system certification through, for example, making use of a generic term where the application of the management system requirements can apply to any one and/or all of the certification schemes. The use of one generic reference would then also simplify the planned incorporation of additional management system certification schemes into the QMS. The recommendation to use the term 'management system certification' was accepted.

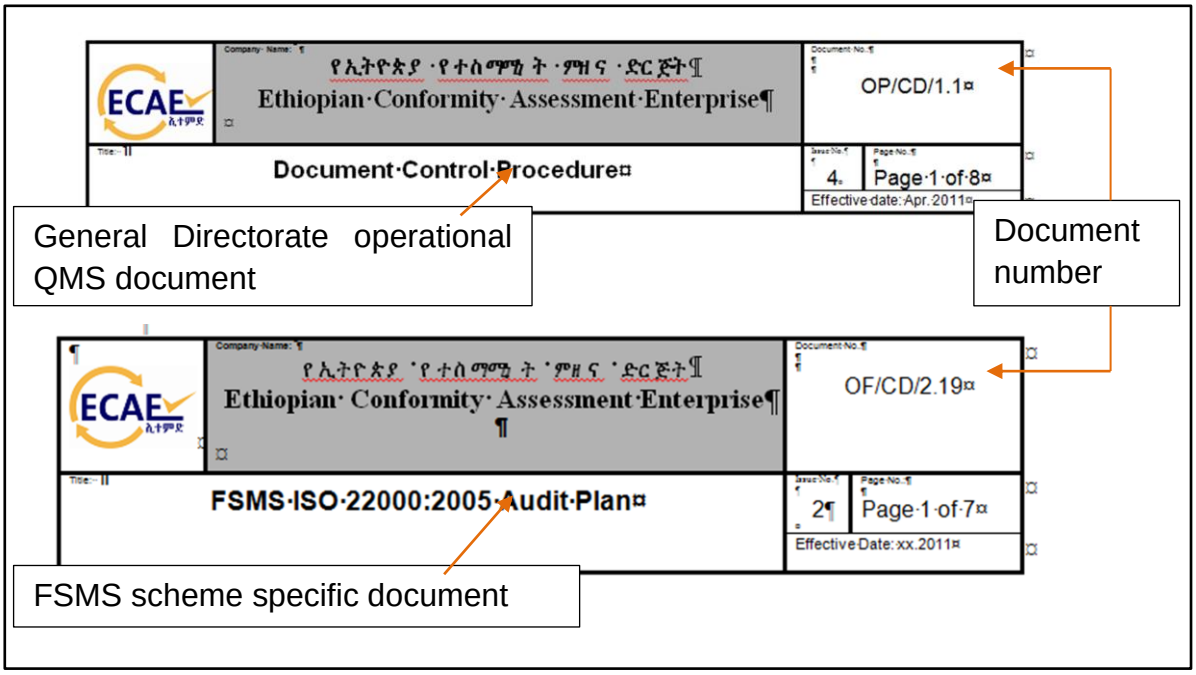


**Figure 10:** Illustration of the identification and numbering of QMS documentation of the Certification Directorate

The format, style and contents in terms of paragraph setup of documentation reviewed reflected an inconsistent application thereof. This was unexpected seeing that the QMS had already been through an accreditation assessment. Consistency in format, style and contents of documentation forms the foundation for the control of documents within a management system. The setting up of document templates based on the four types of documents as reflected by Figure 11 required for the QMS documentation was then recommended. The application of templates by document users is a simple and effective method for ensuring that writers of documents consistently apply the required format, style and contents setup and therefore assists with the control of documents within a management system. The templates were developed and applied during the documentation review process as and when a specific document was reviewed and updated to also then reflect the work conducted as part of point (a) of the study project objectives.

Other than the general format problems, the documentation review revealed that one set of QMS documentation had been designed for the application of the three different types of conformity assessment certifications, i.e. product certification, management system certification, and personnel certification. The management system requirements of these certifications are different in context of application as they are to be built on the requirements of their unique international standards therefore meaning that each one should have its own QMS setting out its unique interpretation and application of the standard's requirements. A recommendation was put forward to split the QMS into the three different categories of conformity assessment and to allocate an 'owner' to each part of the management system of the Directorate. An overall management system design for the conformity assessment Directorate had to be developed to support a more simplified, structural and manageable approach based on the recommendation made. The development of this management system had to also include the normal features for documentation of a management system such as numbering, titles, headers and footers, format, approval authorities, generic documentation, and scheme unique documentation, and had to support the three conformity assessment areas within the Directorate from a Directorate point of view in terms of consistency of documentation within the Directorate but also the uniqueness of certification schemes.

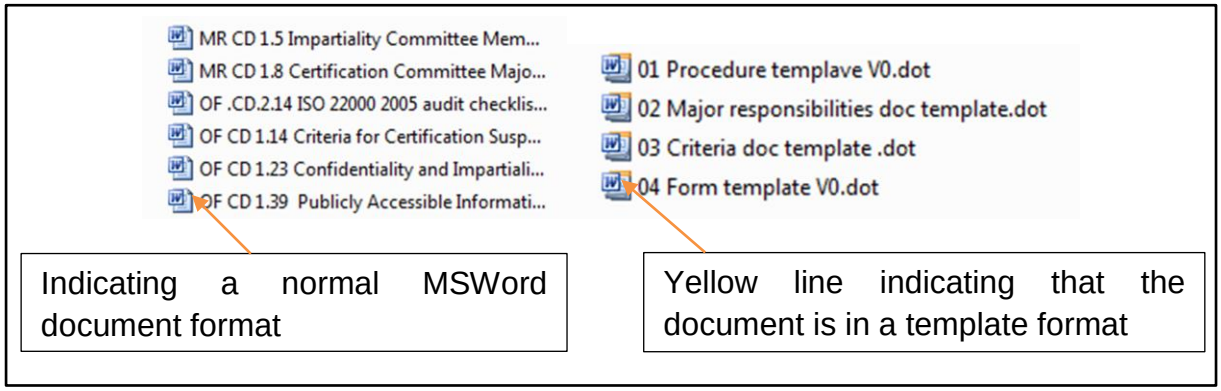


**Figure 11:** Illustration of the difference between normal and template documentation within a management system

This was recommended to support long-term sustainability of the operations of the Directorate and to support individual certifications in terms of their required accreditation. This recommendation was accepted. Electronic versions of the QMS were found on various computers within the certification area. Various versions of the same documents were found on these different computers, an aspect that is not allowed based on the requirements for the control of documents. The availability of documentation and the control of its distribution was an aspect which should have been controlled under the 'control of documents' procedure. As a rule, one master set of documents is kept by the QMS documentation owner, commonly referred to as the Quality Manager. A read-only copy of the QMS is then made available on a network and/or given in hard copy to document users. Also, the method applied for the filing of the electronic versions of documents was found to be very cumbersome and it was difficult to find a document within the system because it was based on an alphabetic methodology as illustrated by Figure 12.

The difficulty in finding documents leads to the development of duplicate documents by the document user for the simple reason that he/she cannot find what is required and/or may carry out tasks in accordance with his/her own interpretation of what needs to occur and therefore not necessarily in accordance with an approved or controlled way reflected by 'controlled' documents. In many cases this results in a breakdown of the operations of the management system which is in terms of maintaining an accredited status not something that is favourable. A simplified method of filing documentation electronically would rather be based on numbers and not an alphabetically filing method, as the prefixes of documents reflect numbers which would also indicate the level of the document and its most appropriate area of application. A recommendation was put forward to firstly identify the 'owner' of the QMS documentation and to then determine a method for making the documentation easily available to users. This included ensuring that an official back-up copy of the QMS documentation be made on a regular basis instead of copying it onto various computers 'for in case' something happens to 'a particular computer' and the QMS documentation is then lost or jeopardised.

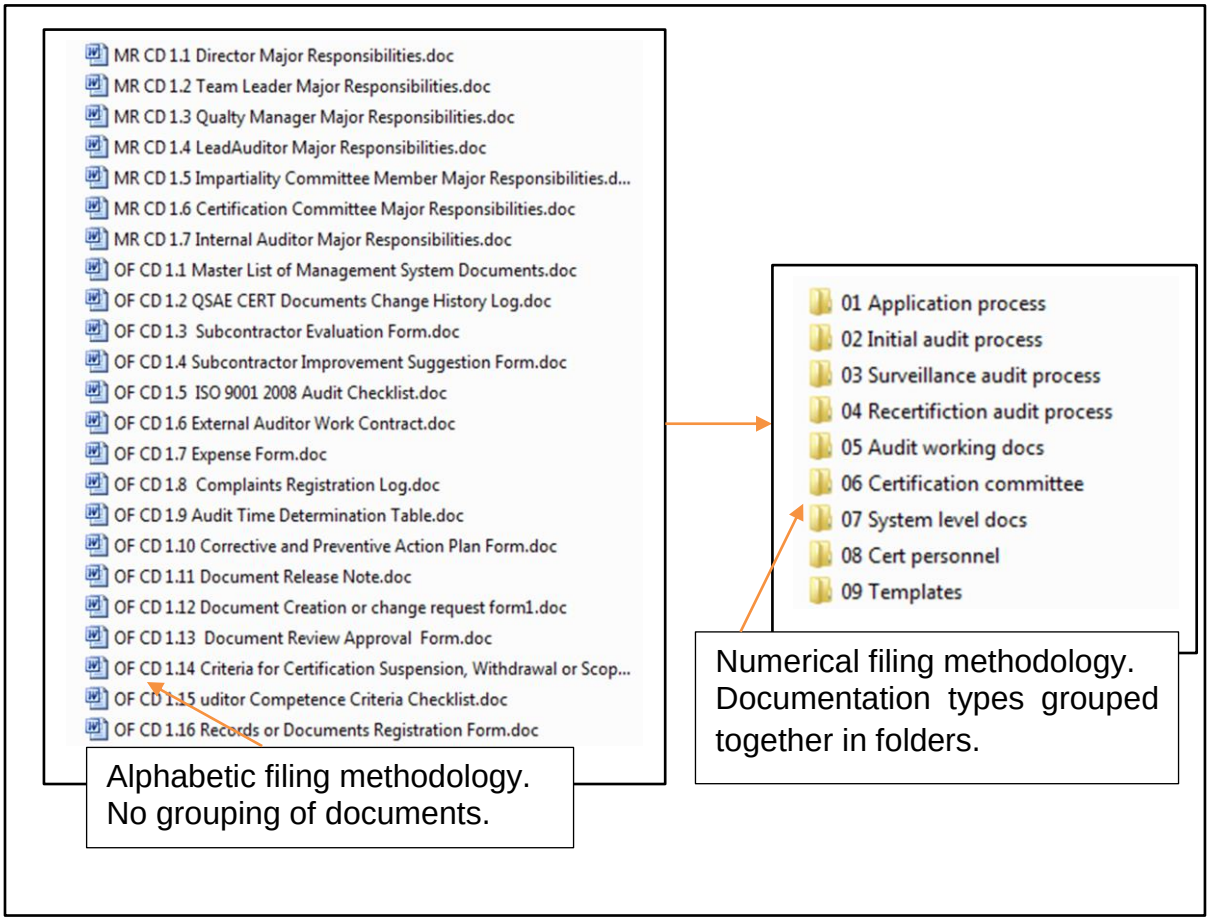


**Figure 12:** Schematic illustration of the simplification of filing methods applied to a set of management system documentation

The accredited status of the QMS in some cases stifled recommendations made towards filling the gaps with documentation problems noted during the document review. This was created by an underlying expectation that certain documents would be present and would contain a certain level and type of information. The review revealed otherwise, and this led to sometimes lengthy explanations and discussions before a document or an aspect of a specific document could be reviewed and then agreed upon. Also, the use of a consultant from Europe through a previous sponsored capacity building project to develop the initial QMS for the purpose of application of the ISO 9001 certification scheme and its accreditation, identified a set of additional problems, i.e. badly constructed sentences due to ineffective translations, language issues and interpretations, duplication of information in documents, general interpretation of the written text, lack of understanding of the Ethiopian specific practices towards certification, lack of understanding what type of information had to be included in paragraphs and if not understood, just left blank, and missing aspects from the requirements of ISO/IEC 17021. This implied that the QMS documentation would need to be corrected before the additional documentation pertaining to the FSMS certification scheme could be added.

The ‘quality’ of the documentation further stifled discussion with the personnel that participated in the documentation review and made recommendations for filling the gaps within the documentation setup difficult as it was believed that the QMS presented was of an acceptable status, based on it being accredited and therefore regarded by personnel of the Directorate as suitable. The expectation by personnel that only the relevant part of the QMS had to be reviewed in relation to the study project objective, i.e. FSMS certification, also stifled the documentation review process in that not all QMS documentation was put forward for review. The review had to take cognizance of the full QMS in order to determine the status and therefore the place where food safety specific activities and actions had to be incorporated into the QMS. This led to the prevention of access to certain documents and the full extent of compliance of the QMS documentation with ISO/IEC 17021 and ISO/TS 22003 could not be provided in the time frame allocated for the document review.

Activities noted in points C4 to C11 of Table 1 were developed to support the completion of work that could not be completed and it was recommended to consider

these actions and discussion points during a documentation structure and planning session with all the relevant certification personnel. The document review took long and, in some cases faced inefficiency as personnel of the Directorate did not want to deviate from any contents of documents owing to the 'approval status' of documents from the accreditation process and 'respect to authority levels' within the Directorate. The document review could therefore not include a complete review and the identification of gaps within the QMS documentation. The review process then turned into the correcting and improving of documents rather than reviewing them and at the same time when a gap was identified, and only when accepted by the levels of authority within the Directorate could the process move forward through completion of a document and/or set of documents relative to a discussion point. Convincing personnel to deviate from, for example the known documentation structure, format, and contents was a challenge and made achieving objective (a) of the study project very complicated.

An overall summary of the findings of the documentation review is reflected in Annexure 3.9.

### 3.3.3 Activity 3: Certification personnel review

Figure 13 indicates the applicable aspects reviewed in this activity and was extracted from Figure 2.


#### 3.3.3.1 Application review personnel

The application review committee is a group of certification personnel who are technically competent in a specific certification scheme to review the applications for certification made by a proposed certification client. Application reviewers are responsible based on the information supplied in an application for making a judgement if certification can be conducted, whether the competencies in terms of auditing and decision-making personnel are available and whether the proposed certification client is able to be certified to the scheme requested and within the scope of their stated management system.

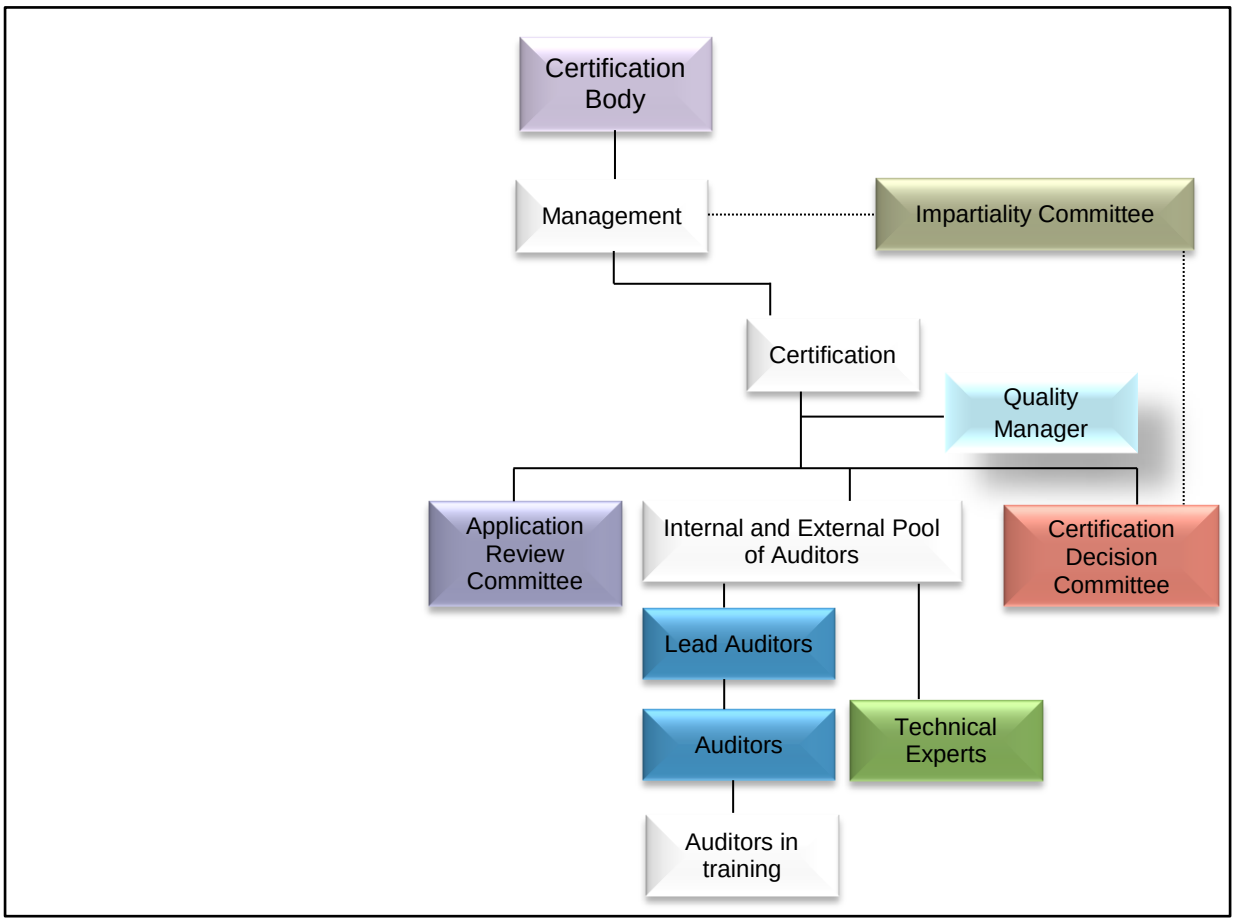


**Figure 13:** Illustration of the certification personnel review aspects relevant to activity 3

The application review personnel used for reviewing the FSMS certification applications were found to comply with the education and audit training requirements of ISO/TS 22003 (2007) noted in Annexure 3.4. What was lacking, however, was that these personnel had not all received food safety training which then implied that their judgement on making decisions about the proposed certification client and the feasibility for their certification was impaired.

The standards further required specific competency requirements for these personnel reflected in Annexures 3.3 and 3.4. These specific competencies could not be verified for these personnel because the FSMS certification scheme was not yet operational and it was therefore difficult to determine if they are in compliance with these competency requirements or not. One specific competency relating to 'the assessment of the applicant's products, processes and practices' and then especially within a specific food chain category as noted in Annexure 3.5 was regarded as problematic because of the overall lack of practical food handling experience of the personnel that were going to conduct the application review. It was then recommended in point B1 of Table 1 to review these required competencies once the scheme became active. A further recommendation included the option to either apply external technical experts in the food handling sector applying for certification or to gain knowledge of the food handling sector through visitation to food facilities, attending short courses and/or studying the particular food handling practices through books, guideline documents or relevant types of information. This gap identified by the review could also be filled through the application of additional capacity building projects or interventions.

#### 3.3.3.2 Certification decision-making personnel

Certification Decision Committee

This committee is formed every time a certification decision is to be taken. This committee may meet on a regular basis, i.e. once a week or once every two weeks and/or even when the need arises. The need for the sitting of this committee is determined by the completion of an audit process as illustrated by Figure 8, therefore a completed stage 1 and stage 2 audit including the completion of the required corrective actions from the proposed certification client. The lead auditor will then prepare the proposed certification client's file in accordance with a predetermined set

of required records which is then submitted to the committee for evaluation and decision whether certification can be awarded or not. The members of this committee are therefore selected based on their specific competencies relating to a certification scheme and industry sector or food chain category relevant to the proposed certification client's details.

Personnel making up this certification decision-making committee for the FSMS certification scheme were selected from the pool of auditors. Details of the full pool of auditors could not be accessed during the review period and it could therefore not accurately be determined to what extent the possible selection of certification decision-making personnel specifically for the FSMS certification scheme was able to meet the certification decision personnel requirements stated by ISO/IEC 17021 (2011) and ISO/TS 22003 (2007) noted in Annexures 3.3 and 3.4 in relation to Annexure 3.5 in terms of the relevant food chain category. Discussions and the review of a selected few personnel from auditor's pool that were active and/or preliminary selected to be part of the committee did, however, indicate that they were not able to comply with most of the ISO/TS 22003 requirements. Records towards the compliance of the terminology, knowledge and skills aspects of specific competencies were found to be lacking and this could purely be owing to the lack of practical and theoretical food safety and then specifically ISO 22000 training received by the proposed nominated committee members. This result implied that the certification decision-making personnel selected to make FSMS certification decisions will not be able to make effective decisions on certification for the FSMS certification scheme. Recommendations similar to the application review personnel's review results were made in point B2 of Table 1.

Impartiality Committee

#### 3.3.3.3 Impartiality committee personnel

Although the impartiality committee personnel do not form part of the personnel of the Certification Directorate, their review was included under the review of personnel because of their relevance to the overall compliance with ISO/IEC 17021 and ISO/TS 22003. The impartiality committee consists of people selected from management system certification interested parties who are selected to participate as objective individuals that can oversee and make judgement on the impartial

operations of the CB. This committee meets once or twice a year and will operate in accordance with set criteria established by the certification personnel as an integral part of the QMS.

An impartiality committee was already established owing to the accreditation of the QMS certification scheme. This committee had to function as the overall impartiality committee and that implied that the FSMS certification scheme activities were going to be included in the committee activities. The membership of the impartiality committee reflected a 50% government and 50% non-government representation. The committee membership also included members representing the food industry and was therefore overall found to be adequate and in compliance with the certification requirements. The membership included representation from the following:

a. Ministry of Health,
b. Ministry of Agriculture,
c. Minister of Education,
d. Ethiopian Chamber of Commerce,
e. National Association of Ethiopian Industries,
f. Consumer Protection Association,
g. ECAE Quality Manager – secretary (non-voting), and
h. ECAE Team Leader Certification – resources and information supply (participant only).

#### 3.3.3.4 Auditing personnel

Internal & External Pool of auditors

Auditing personnel include a combination of auditors in training, auditors and lead auditors. These are all phases of an auditor's career. The type of auditor are responsible for carrying out certain aspects of an audit based on an audit plan, and this can include observation, auditing the production processes or the management system aspects and leading a team during an audit. The lead auditor is normally responsible for establishing the audit plan, leading the opening and closing meetings, managing the audit team during the audit in addition to carrying out his/her part of the audit, concluding the audit outcome through preparation of the audit

report and then assembling of the required records in preparation of the audit client's file that are then submitted to the certification decision committee for the final certification decision. The competency of auditors plays an integral role in the certification process and has a direct impact on the accreditation of the CB as it remains the focus point of accreditation. Competency requirements for FSMS auditors are particular in terms of their education, food safety training, audit training, work experience and auditing experience. These requirements are stipulated by ISO/TS 22003 (2007) and are further to be related to the specific food chain category for which the certification will take place.

Other than the certification personnel of the Certification Directorate, i.e. the director, team leader and quality manager, a pool of 87 auditors reflecting a combination of auditor types as well as technical experts was in place at the time of the review. The pool included auditors from the Certification Directorate, which are referred to as internal auditors and then also auditors form other areas of the organization such as standards, laboratories or other conformity assessment areas as well as auditors from outside the organization which are referred to as external auditors. This pool of auditors was mainly being used for the auditing of the QMS certification scheme and therefore reflected the compliance with competency requirements for this scheme. The competency requirements for the QMS certification scheme were mainly based on requirements set out in ISO/IEC 17021 (2011) and ISO 19011 (2011). The requirements for FSMS certification scheme auditor competency were to be based on these requirements and also had to be supplemented by ISO/TS 22003 (2007).

What was known by the expert at the time of reviewing the auditing personnel, was that some of the general certification personnel had received training on HACCP based on the South African National Standard, SANS 10330 in South Africa in 2002 as well as training by the same training provider in 2004 in Ethiopia on ISO 22000 in particular with the majority of the same learners as for the HACCP training. What was then found during the review was that a number of these trained individuals had since this training left the employment of the ECAE. The majority of the remaining trained individuals had not since receiving the training been exposed to any certification activities, and especially, FSMS certification activities. It was therefore highly likely that the training on food safety in relation to ISO 22000 and its

certification methods had to be repeated in order to support the declaration of competency of auditors for the FSMS certification scheme. It was recommended to ensure firstly that the correct auditors in terms of the competency requirements stated in the standards are selected before the training is repeated. This training could easily be done within the organization as part of the QMS procedures relevant to auditor competencies.

Time and the fact that specific food safety auditors had not yet been selected did not allow for the full review of auditor profiles in the auditor pool and especially not to the level of detail noted by the criteria of Annexures 3.3 to 3.7. For the purpose of the review and especially for the study project objective (b), a selection of capable auditors from the pool was made by the team leader and was therefore included in the review. These auditors were reviewed against the specific criterion for food safety auditors noted in Annexure 3.4 in relation to Annexure 3.5. Focus was placed on the main auditor requirements, i.e. audit principles, procedures and techniques, management system and reference documents, organizational situations, applicable laws, regulations and other requirements relevant to the discipline and also the specific terminology, knowledge and skills competencies.

The review revealed the following results also illustrated in summary by Figure 14:

a. Audit principles, procedures and techniques

These requirements are needed to enable the auditor to apply the requirements to different audits and to ensure that audits are conducted in a consistent and systematic manner. From the 13 requirements, 11 were seen to be based on general auditing principles, processes and methods based on ISO 19011 leaving the reviewed auditors competent as these requirements also pertains to the QMS certification auditors and the pool of auditors used by the Directorate had already indicated compliance with these requirements. The two remaining requirements focused on the understanding of food safety, FSMS and its application to analyse the audit data collected so that the consequences of the data can be interpreted for the purpose of making appropriate audit outcome recommendations. Competency in these aspects

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| | could not be confirmed. |
| b. Management system and reference documents | These requirements are needed to enable the auditor to comprehend the scope of the audit and apply the audit criteria effectively.<br>From the six requirements, one seemed to comply and five pertained to the understanding and application of ISO 22000. Some of the auditors reviewed have received ISO 22000 training, which, however, was a few years prior to this project and they had never applied the knowledge learnt after the training. Some of the other auditors who formed part of the review were not compliant based on their education, working and auditing experience even though they have been trained on ISO 22000. This was therefore regarded as a non-compliant result. |
| c. Organizational situations | These requirements are needed to enable the auditor to comprehend the organization's operational context during an audit.<br>From the three requirements, two were considered to be in compliance. The third requirement was based on the processes and terminologies of the organization and its processes being audited where the auditors reviewed could not yet demonstrate the application of ISO 22000 knowledge in an organization owing to the fact that the FSMS audits had not yet been conducted. |
| d. Applicable laws, regulations and other requirements relevant to the discipline | This requirement is needed to enable the auditor to work within and be aware of the legal requirements applied with the FSMS.<br>From the four requirements, one could be considered to be in compliance. The other three could not be demonstrated based on the lack of overall knowledge of legislation for food safety and then especially within a specific food chain category. |
| e. Competencies – terminology, | This requirement had 11 requirements pertaining to food safety terminology based on ISO 22000. Compliance with |

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| knowledge and skills | these requirements could not be demonstrated based on the fact that no FSMS audits had been conducted, the training of some of the auditors had lapsed and the other possible auditors had not received ISO 22000 training. |

It was therefore in general found that the auditors selected for the review did not yet comply with almost 59% of the food safety specific requirements for auditors set in ISO/TS 22003 (2007). Recommendations in point B4 of Table 1 was made that a more extensive evaluation of the pool of auditors be conducted. Discussions also included accessing auditors from outside the organization in order to support all the requirements of ISO/TS 22003 (2007), especially the work experience requirements. A comparison between the 'immediate competent' versus 'competent after training' was recommended to also set the required training requirements needed for auditors and then to conduct training so that the competency of auditors can be reached within a set period. Specific attention will have to be given to the specific food chain categories noted in Annexure 3.5 as this would form an integral part of the competency evidence of the auditors. The FSMS certification scheme can only move forward once auditor competencies in line with ISO/TS 22003 can be demonstrated.

Based on the review of the auditors and the general fact that the majority of the employees of the ECAE did not in particular have food industry related work experience, further recommendations were made to draw up general audit work experience criteria based on the reflection of the current pool of auditors that may be used for FSMS auditing versus the need for work experience based on the food chain categories that are to be audited against. These criteria may support the overall assessment of the pool of auditors and will also support the required training for auditors that is to be conducted to meet the FSMS auditor criteria. If then not internal to the ECAE, resources externally may need to be acquired. An option towards the search for external auditors included the placement of an advertisement in the local and national newspapers, evaluating the IRCA registered auditors and/or a collaboration with other accredited CBs to use their auditors in order to build capacity within the Certification Directorate.

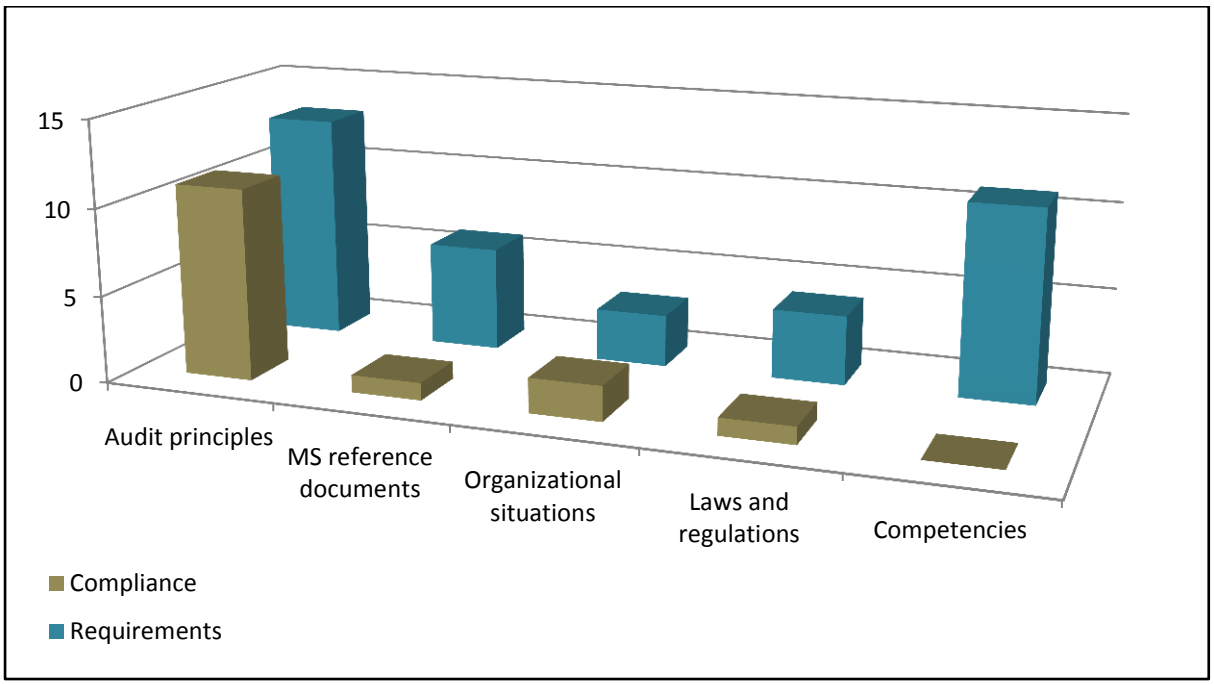


**Figure 14:** Comparison between the requirements and compliance of competencies of food safety auditors

An additional obstacle to the competency requirements identified during the review was the fee structure available for use of external auditors. The fee structure for certification and the use of these external auditors were predicated by Government and could therefore not be changed. The current certification and external auditor fee structure was not seen as being market related, i.e. the auditor fee structure reflected about a third of market-related fees for external auditors. The fee structure will not be attractive to external auditors meaning that the Directorate will not be able to use the external auditor market in support of having sufficient competent auditing resources. Sufficient competent auditing resources form part of the requirements of ISO/IEC 17021 (2011) and therefore also the accreditation criteria in terms of the 'capabilities' of the CB to provide certification activities. The use of external auditors where fees are to be paid relevant to the market expectation would place an extreme financial burden on the Certification Directorate as the income derived from certification activities would lean towards a negative growth. It was therefore recommended to revise the fee structure for certification activities.

The use of external auditors would also have an impact on the QMS aspects such as intellectual property, service and auditing quality, confidentially and impartiality, which indicated the seriousness of having access to competent auditing personnel. Having access to external resources is, however, of relevance to the sustainability of the FSMS certification scheme as it makes business sense to have access to external resources rather than employing auditors full-time and only applying them for a particular audit, especially for food safety due owing competencies based on the food chain categories. The risks of using external auditors had to be considered and it was recommended that in order to mitigate these risks a legal agreement stating the auditing expectations, requirements, rules and processes of the Directorate had to be drawn up and put in place. Another factor that had to be taken into account was the ongoing training of these external auditors, commonly referred to as having 'calibration sessions' in combination with the internal pool of auditors. This would be required to ensure consistency of application of certification activities between external and internal auditors. Calibration session 'contents' had to be considered and placed as requirements for ongoing training on the QMS.

A list of competent auditors and/or plans to achieve their competencies could only be communicated to the accreditation body for evaluation once a more certain pool of FSMS specific auditors could be collated. The application of the recommended evaluations and setting of criteria to ease the evaluation and ongoing training processes will support the ongoing progression towards achieving competency and therefore accreditation towards FSMS certification.

#### 3.3.3.5 Technical experts


Technical experts are non-auditing personnel who are considered especially knowledgeable in a field and are used by audit teams to support auditors with technical information on the processes being audited. The competency requirements for technical experts noted in Annexure 3.4 are therefore not as complex or specific as for those of auditing personnel and they therefore need not go through all the various auditing training. This means that these individuals can be used sooner and fewer resources spend on them in order to ensure their competency in relation to the requirements of ISO/IEC 17021 and ISO/TS 22003.

By reviewing the available pool of auditors, no individual was declared as being a technical expert, and/or a technical expert category had not been set up as being part of the auditing personnel pool. It was recommended in point B4 of Table 1 to use the assessment of the auditing personnel pool to identify individuals that may be used as technical experts to support the acceleration of application of competent audit teams, especially for food safety and then in relation to competencies that had to be available in a specific food chain category. The dilemma remained the provision of evidence to support competency in a specific category, especially for technical experts.

### 3.3.4 Activity 4: Two-day orientation session

A two-day orientation session was conducted on the discussions of the facility visit outcomes, basic concepts of food safety, interpretation of certain clauses of ISO 22000 (2005), the role of food legislation, other related standards and customer requirements in relation to the requirements of ISO 22000 and food safety, as well as

the procedural training on the QMS documents developed during the study project period.

During the planning of the two-day orientation session, the participating personnel found it to be valuable to include people external to the ECAE. This decision was based on an introductory session to food safety held for the ECAE personnel earlier during the study project period. The personnel felt that the relevant external people will benefit from this session and will also announce that the ECAE is in the process of preparing to certify FSMSs in Ethiopia. The participation of the external people was planned to only include a half-day discussion where the FSMS relevant information of the proposed certification scheme would be discussed. The combined internal and external people invited to this orientation session included representatives from the testing laboratories, system certification, product certification, technical experts, top management of the ECAE, lecturers and instructors from the Addis Ababa University, food handling organizations interested in FSMS certification, the Ministry of Industry, an agri-processing industry expert, a food manufacturing expert from the Food and Drug Control Authority, and an analyst from the Ministry of Agriculture.

The actual orientation session led to a one-and-a-half-day discussion session on ISO 22000 (2005) and the interpretation of its clauses, relevant food legislation, other standards, PRPs, and examples of expected documentation for the purpose of implementation and the certification of an FSMS. After this discussion session, half a day was spent on the orientation of the certification personnel on the application of the QMS procedures and processes developed as part of the study project. This half-day session was only intended for ECAE personnel, however, due to the time spent on the extended discussions prior to this session, insufficient time was available to thoroughly expose the certification personnel to the FSMS certification documents and activities.

The advantage of this orientation session was that the ECAE received well-needed exposure to the relevant parties invited to the session, however, the disadvantage of this orientation session was the lack of proper exposure of the FSMS certification documents and activities to the certification personnel. This meant that another

orientation session for the certification personnel had to be planned and conducted in order to ensure that the required capacity had been built towards the FSMS certification scheme operations and therefore its accreditation.

The introductory session conducted to ECAE personnel prior to the two-day orientation session included 13 ECAE personnel from various departments and levels of management. This session was an informal discussion session on food safety and touched on aspects such as food safety in general, food safety concepts, food safety hazards, food-borne diseases and the burden of food-borne diseases, principles of management systems, HACCP and the contents of ISO 22000 with a bit more attention to the identification of the various controls for food safety hazards such as PRPs, critical control points (CCPs) or operational PRPs. Discussions with the group further included aspects found during the study project to be explored in order for the FSMS certification scheme to move forward. These aspects included (i) the food chain categories relevant to Ethiopia and the priorities of the Government in support of food trade, (ii) Ethiopian food legislation and the relevance of the ECAE in playing a role in establishing suitable food laws, (iii) the need for food testing as well as the probability of the uncertainty of sampling and testing in ensuring accurate results on the presence of food safety hazards in foods, and (iv) possible obstacles for the certification department in concluding the development, implementation and accreditation of the FSMS certification scheme.

Further training on the contents of the QMS and its application towards FSMS certification had to be conducted. This could only be done after completion of the QMS and all the relevant FSMS certification activities. Training would need to be extended to the certification personnel on the understanding and application of ISO 22000, its supporting standards and legislation, but only once a final decision had been made on the nominated auditors that could be declared competent in terms of the requirements of the standards and the criteria set out in the QMS.

### 3.3.5 Activity 5: Food manufacturing facilities

Three food manufacturing facilities were selected by the ECAE personnel for this activity. Two of the three facilities had already implemented ISO 22000 (2005) and had been certified to this standard by a South African CB that was accredited for

FSMS certification. One facility was in the process of becoming certified to ISO 22000. For each facility, six to eight nominated ECAE certification personnel participated in the exercise with some having exposure to all three facilities and others just to one or two facilities.

The visits were approached with a typical certification assessment scenario where the outside perimeters of the facility were inspected first for adequacy towards PRPs and then moved into the food handling areas where the various food handling activities and processes were observed in relation to food safety hazards, PRPs, CCPs and operational PRPs. Office discussions took place after the facility walkabout where the assessment team was given an opportunity to have open discussions on the FSMS development, implementation and certification processes with a nominated member of management of the facility. The office discussions allowed the assessment team to see and page through the FSMS documentation of the facility and to be exposed to the perceptions and experience of an audit client on the benefits, applications and difficulties of the certification process. The assessment team could evaluate and discuss details of the HACCP studies and their outcomes, general system, process and audit nonconformities, customer interaction, application of other relevant standards and legislation as well as how to handle difficult activities within a certified FSMS, such as ongoing food safety team meetings, improvements, and updates.

The first two facilities had assistance from an Ethiopian based FSMS consultant with the implementation of their FSMS. Both these facilities initiated their FSMS activities based on the South African National Standard for HACCP, SANS 10330 (2007), and its supporting document for PRPs, SANS 10049 (2012). The implementation and certification of these FSMSs had already been completed and awarded five years prior to the upgrading of their systems in accordance with ISO 22000. They have already been certified against ISO 22000 for three years. The FSMS consultant received most of his food safety training in South Africa, which not only made the FSMS of the two facilities similar, but also very much based on South African FSMS application methodologies. It was therefore appropriate for the South African CB to have successfully certified the FSMS of these two facilities. The third facility did not use the services of an FSMS consultant and the FSMS activities observed were

different from the first two facilities and were unique to the application of the facility specific operations and food handling practices.

A full ISO 22000 audit typical to an FSMS certification process could not be conducted during the facility visits owing to the combination of the time allowed for the visits and the capacity building training that had to take place with the assessment team during the on-site visitation period. The assessment team was, however, able to identify a typical PRP, reflected by some of the photographs on pages 129 and 130, ISO 22000 and certification requirement inadequacies during the visitation period at the facilities. Annexure 3.8 includes a summary of the contents of ISO 22000 (2005) and ISO/TS 22002-1 (2009) used to audit the facility. A bit more time was spent on looking at the HACCP of the facilities to give the assessment team some exposure to what the outcome of a HACCP study could typically look like. The capacity building training then focused on supporting the assessment team with the analysis and interpretation of the identified inadequacies and the implications for certification, should the audit clients not have been certified. The role and impact of the use of FSMS consultants were also part of the discussions because similar inadequacies were found between the first two facilities that were already certified.

What were also realized during the facility visits were the possible difficulties for the ECAE to initiate and sustain its FSMS certification scheme in Ethiopia based on, maybe initially, convincing food facilities to receive ECAE certification instead of certification from other countries, such as South Africa, especially if its certification had been in place for some time. Long-term certification through a CB creates a means of trust and understanding in how the certification audits are conducted and how the auditors then assess the information supplied to them. The risk for the audit client to change the CB lies in the possibility that the new audit team will assess the information supplied slightly different and may even imply that its certification status can be jeopardised. This was especially evident after the facility visits as various aspects of the observed areas and documents of the certified facilities have been considered by the ECAE assessment team to be inadequate and/or not compliant with the requirements of ISO 22000 (2005).

Trust will have to be built in the market place that the ECAE is capable of assessing FSMSs and certifying food facilities based on their competency and that they are operating on the same principles and against the same standards as CBs already operating in the country. The transfer of certification also includes specific requirements stipulated by ISO/IEC 17021 where an already certified food facility can be transferred to another CB based on these requirements. The problem is that this certified facility could be found not to comply with all the relevant requirements of the 'new' CB and its criteria leading to conflict and possible mistrust, in this case against the ECAE. The application of audit time, commonly referred to as 'man-days', may also be interpreted differently between CBs leading to either very cheap certification or very expensive certification as costs are mostly determined based on the man-day allocation of the CB. ISO/TS 22003 (2007) stipulates how to determine the man-day allocation, however, has been found in the certification industry not to be followed based on the market competition for certification. The majority of the food facilities select their CB based on costs and this could therefore support the growing certification market, or it can stifle the growth. Some level of inconsistency in the interpretation of the certification requirements exists between CBs and their auditors, and this may also lead to a change in certification status of audit clients between CBs.

The result of the facility visits was regarded firstly as positive towards the exposure of the assessment team to ISO 22000 in practice. Secondly, it identified some problems in the certification market place which in a way was also positive as it would give the ECAE an opportunity to deal with these issues with the aim of developing its FSMS certification scheme and therefore also the means of entering the certification market. Point D3 of Table 1 reflects some of the recommendations done in support of growing the certification market for food safety.

**Facility 1:** Oil-manufacturing facility

Assessment team

Uncut grass – pest control

Deteriorated flooring

Open doors while filling the end product

Broken glass on desk inside the manufacturing area

Use of non-food safe cleaning equipment

Laboratory assistant collecting samples from the manufacturing area

Personal clothing, jewellery and open shoes worn by female staff

Small carpets on floors in packing area

**Facility 2:** Baby food manufacturing facility

Assessment team

Uncut grass – pest control


Raw material identification

Open machinery parts on the outside of the manufacturing facility

Uncovered light fittings

Deteriorated flooring

Female workers wearing jewellery

Birds inside food handling areas

Temporary fixtures to machinery

**Facility 3:** Airline catering facility

No photographs were allowed to be taken at this facility. The majority of the PRPs were found to be suitably dealt with. Food handling practices were of a more sophisticated state.

### 3.4 Project study outcome recommendations made

The recommendations made as an outcome of the analysis were categorized into four main categories, illustrated by Figure 15.

These four categories were then populated with detailed information to support the certification personnel with the needed guidance to complete the development of the FSMS certification scheme. The details of this action item list that had to be dealt with are noted in Table 1.

Some of the recommendations noted in this action item list and the noted information in Annexure 3.9 were dealt with during the project study 1 period as part of the project work activities. The remaining items of both these summary and recommendation documents had to be actioned by the certification personnel over a mutually agreed predetermined period of about eight months, which are reflected in Table 2. The action item list, including the summary of the documentation review reflected in Annexure 3.9 was going to be used to set the tone for the planning of the study 2 project period.

A total of 114 action items were recommended. Other than for the general FSMS certification scheme items, a nearly equal number of action items illustrated by Figure 16 had to be dealt with for the categories resulting from the gap analysis. The certification personnel were given an opportunity to allocate their required target dates for the actioning of these items over the agreed eight months based on their capacity and those partaking in the processes relevant to the establishment of the certification scheme.

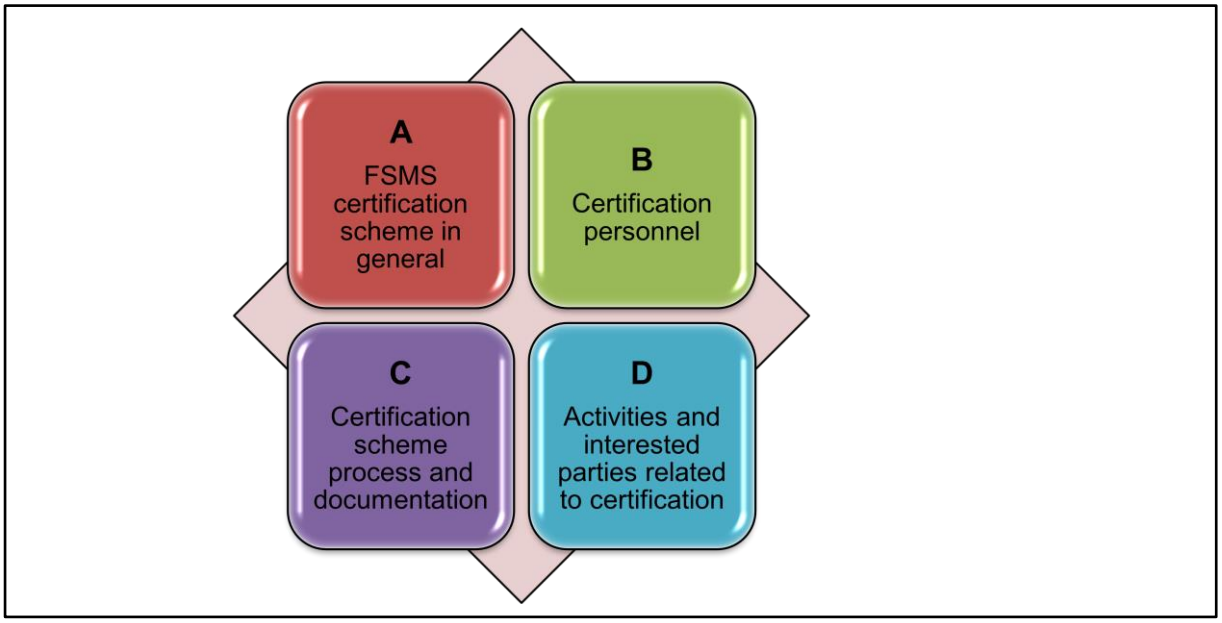


**Figure 15:** Illustration of the four main categories as part of the recommendations of the project study 1 gap analysis outcome

**Table 1:** Project study 1 action item list of the gap analysis outcome recommendations

| No | Action items |
|---|---|
| **A** | **Food safety management system certification scheme in general** |
| 1 | Identify a specific nominated person (project champion) to take the project forward to accreditation |
| 2 | Nominate relevant participants of the project and determine biweekly project follow-up actions or meetings to pace the completion of the project |
| 3 | Identify a more detailed action item list, time frame and detailed responsibilities for the completion of the project |
| **B** | **Certification personnel** |
| **B1** | **Application review committee members – Quality Manager – Certification** |
| 1 | Identify an adequate pool of reviewers that comply with the education, food safety training and audit training criteria of ISO/TS 22003 |
| 2 | For those who do not have food safety training, schedule, ensure that they attend, and verify such training |
| 3 | For those who do not have audit training, schedule, ensure that they attend, and verify such training |
| 4 | For the pool identified, schedule the assessment of their competencies as stipulated by 7.2.2.4 of ISO/TS 22003 (2007) |
| 5 | Establish corrective actions for those individuals who do not comply with the competency evaluation |
| **B2** | **Certification decision committee – Team Leader – Certification** |
| 6 | Identify an adequate internal pool of certification committee members that comply with the education, food safety training, audit training and work experience criteria of ISO/TS 22003 – within the food chain categories selected |
| 7 | Identify an adequate external pool of certification committee members that |

| No | Action items |
|---|---|
| | comply with the education, food safety training, audit training and work experience criteria of ISO/TS 22003 – within the food chain categories selected |
| 8 | For those who do not have food safety training, schedule, ensure that they attend, and verify such training |
| 9 | For those who do not have audit training, schedule, provide and verify such training |
| 10 | For the pool identified, schedule the assessment of their competencies as stipulated by 7.2.3.2 of ISO/TS 22003 (2007) |
| 11 | Establish corrective actions for those individuals who do not comply with the competency evaluation |
| **B3** | **Impartiality committee – Director – Certification** |
| 12 | No action needed |
| **B4** | **Auditors – Team Leader – Certification** |
| 13 | Evaluate current internal auditor pool against the education, food safety training, audit training, audit and work experience requirements of ISO/TS 22003 |
| 14 | Advertise externally to the organization for auditors and technical experts |
| 15 | Collect and review the external applicants in terms of education, food safety training, audit training, audit and work experience in accordance with ISO/TS 22003 |
| 16 | List the external applicants against the selected food chain categories – also list other possible categories that are available |
| 17 | From the list of the internal pool and the external applicants, list all candidates that can be considered able to qualify as auditors and technical experts |
| 18 | Draw up a list of acceptable courses of education as well as acceptable institutions that do and will comply with the requirements of ISO/TS 22003 – use these criteria as internal criteria for the acceptable education requirements |

| No | Action items |
|---|---|
| 19 | From the final list of possible acceptable candidates – For those who do not have food safety training, schedule, ensure that they attend, and verify such training |
| 20 | From the final list of possible acceptable candidates – For those who do not have audit training, schedule, ensure that they attend, and verify such training |
| 21 | From the final list of possible acceptable candidates – For those who do not have audit experience, plan on how the audit experience can be gained |
| 22 | For those who do not have the immediate correct work experience, set up equivalent work experience such as retailing, inspection or enforcement. Determine how to meet the required work experience for those who are lacking |
| 23 | For the final pool identified, schedule the assessment of their competencies as stipulated by 7.2.2.4 of ISO/TS 22003 (2007) |
| 24 | Evaluate the list of registered auditors on the IRCA list to determine auditors and experts in Ethiopia and/or countries surrounding Ethiopia |
| 25 | Communicate with the auditors on the IRCA list to determine their interest in auditing for the ECAE |
| 26 | Identify a pool of experts (internal and/or external) in the selected food categories as it may be used for the purpose of auditing and certification decisions for each certification client. Estimate two nominations per category |
| 27 | Communicate to the accreditation body the proposed auditor criteria and action plan to achieve compliance with ISO/TS 22003 |
| 28 | Determine the general fees paid to external auditors in the certification market |
| 29 | Benchmark the market fees against the current allowed fees to be paid for external auditors or experts |
| 30 | If required, request a fee revision for external auditors and experts in order to match the general fees in the industry |
| 31 | Set up auditor or expert agreements for the selected external auditors or experts |

| No | Action items |
|---|---|
| 32 | Ensure that the external auditor or expert agreement stipulate the required rules and requirements to protect the interest of the ECAE and the audit client |
| 33 | Determine the time frame and methodologies for establishing 'calibration' sessions for auditors and experts |
| 34 | Determine the contents of calibration sessions and/or the means to identify calibration session contents |
| 35 | Develop a list of technical experts relating to the selected food chain categories |
| 36 | Nominated audit teams for each food chain category would need to indicate overall compliance with the 'selection of audit teams' requirements of 7.2.6 of ISO/TS 22003 (2007). Predetermination of such teams are recommended |
| **C** | **Certification scheme process and documentation** |
| **C1** | **Certification schemes – Director – Planning and marketing** |
| 1 | Determine the need for a particular food safety certification scheme |
| **C2** | **Brochure – Director – Planning and marketing** |
| 2 | Review the contents of the brochure to meet the ECAE information |
| 3 | Review the explained certification process in comparison with the new process included in the quality manual and the certification agreement during the site visit |
| **C3** | **Certification certificate – Director – Planning and marketing** |
| 4 | Investigate a suitable means of ensuring authenticity of the certificate |
| **C4** | **Quality manual – Quality Manager – Certification** |
| 5 | Review the quality manual as the contents in terms of layout have been changed, some paragraphs have been shortened to only give a basic description and reference to the particular procedures was included, however, not all the numbers may have been included |
| **C5** | **Documentation in general - Quality Manager - Certification** |
| 6 | Plan a session for the overall structure development for documentation of the |

| No | Action items |
|---|---|
| | Certification Directorate to identify the generic documents, scheme specific technical documents, levels of documents within the directorate and departments and then the possible unique identification in terms of prefixes and numbering |
| 7 | Review the FSMS documentation and the initial QMS documents and compare them in order to identify possible contradictions and especially where the new ISO/IEC 17021 requirements had been incorporated |
| 8 | Ensure that all reviewed and updated documents reflect the document history as 'Reviewed and updated to reflect incorporation of the FSMS certification scheme' with the authors and the effective date of 'Sept 2011'. |
| 9 | Review all documents to ensure that the writing style is 'eurostile' and in font size 12. Add this information to the control of documents procedure as part of the writing requirements of a document |
| 10 | Review all documents to ensure a standard use of the template for the contents of documents |
| 11 | Decide on the identification of documents in terms of the prefixes to add or not to add 'Q' for QMS specific documentation and 'FS' for FSMS specific documents |
| 12 | Review all documents and replace ISO/IEC 17021:2006 with the 2011 version |
| 13 | Review all documents and add ISO/TS 22003 as a reference document |
| 14 | Review all documents and add the IAF mandatory references to where they are appropriate to the specific document |
| 15 | Review all documents to ensure that accurate reference is made to 'referenced documents' for each document and that ISO 9001 or ISO 22000 is not included if it does not influence the use to the specific procedure |
| 16 | Review all documents to ensure the use of the new reference to the certification documentation as 'management system certification' documentation |
| 17 | Decide on the purpose, use and actual contents of paragraph 5, Indicators, of all procedures |

| No | Action items |
|---|---|
| 18 | Review all documents to ensure that the listed abbreviations under point 6 of the procedures are used in the body of the document and/or where abbreviations are used in the body of the document, and that they are listed and explained under point 6 |
| 19 | The approval block appearing in documents seems to move around depending on the user and/or during printing. Ensure that the typing format of this block changes from a 'picture block' to a 'table block' as this will assist in keeping the approval block in one place during the use and printing of documents. Review and correct all documents to ensure that the approvals block remain in the same place. |
| 20 | Review all procedures to remove bullet points in the process description paragraphs and replace them with 'enters' so that each new sentence starts at the left-hand side of the column |
| 21 | Review the stand-alone vision, mission, quality policy, impartiality policy and confidentiality policy as those contained in the quality manual were minimally corrected in terms of the English |
| 22 | Review documents against the comments and recommendations made in the document review list as some were dealt with and some may still need to be discussed and decided on |
| **C6** | **Electronic versions of documents – Quality Manager – Certification** |
| 23 | Identify the QM to be the 'master' holder of electronic versions of all documents |
| 24 | Determine the documentation filing set-up in order to clearly identify general management systems, quality specific and food safety specific documents |
| **C7** | **Management review – Quality Manager – Certification** |
| 25 | Ensure that the next management review includes aspects of food safety certification activities |
| **C8** | **Internal audits – Quality Manager – Certification** |
| 26 | Establish an audit programme reflecting areas and processes of importance |

| No | Action items |
|---|---|
| 27 | Update the internal audit checklist to reflect the requirements of ISO/IEC 17021 (2011) as well as the specific requirements of ISO/TS 22003 (2007) |
| 28 | Establish and document internal audit selection criteria |
| 29 | Keep opening and closing meeting agenda and attendance registers |
| 30 | Update the process flow diagram for the internal audits |
| 31 | Ensure the availability of an internal auditor with a background in the food safety specific requirements, not only of ISO 22003, but also the technicalities of the audit documentation for ISO 22000 |
| **C9** | **Corrective and preventive action – Quality Manager – Certification** |
| 32 | Split the corrective action process from the preventive action process |
| 33 | Develop an internal corrective action form |
| 34 | Develop an internal preventive action form |
| 35 | Define corrective action and preventive action |
| **C10** | **Customer surveys – Quality Manager – Certification** |
| 36 | Establish, for example, an 'excel' spreadsheet containing a list of the customers with their identify numbers (i.e. the application number) and then the 'year' numbers in order to establish a selection matrix to indicate which customers over a period of years have been selected to participate in the surveys. The list will permanently be extended as customers are added. Colours may be used to indicate if customers have been suspended or extended or have a decreased scope, as their certification status may influence the selection of participating in the survey process |
| 37 | Correct the number for the survey form to be a '1' instead of a '2' |
| **C11** | **Auditing processes – Quality Manager – Certification** |
| 38 | Keep the opening and closing meeting attendance register<br>Add a column to the form to indicate signature for opening meeting and signature for closing meeting |
| **D** | **Activities and interested parties related to certification** |

| No | Action items |
|---|---|
| **D1** | **Standards and library – Head – Documentation and publications** |
| 1 | Communicate with the standards body to generate and/or adopt standards for PRPs |
| 2 | Make the required or selected standards available |
| **D2** | **Training and consultation programmes for FSMS – Training and technical support directorate** |
| 3 | Update the training materials to reflect ISO 22000 specific HACCP plan requirements versus only using Codex examples |
| 4 | Plan to reattend a five-day training session to establish 'correctness' of information trained so that it is not in conflict with certification expectations |
| 5 | Plan to have the training provider observe one or two FSMS certification audits in order to verify contents of the training material against the certification processes |
| 6 | Plan for the participation of the consulting personnel to participate in training and auditing activities in order to ensure correct implementation recommendations to the certification client |
| **D3** | **Ethiopian food handling market, marketing and new business development – Director – Planning and marketing** |
| 7 | Investigate the need and readiness for ISO 22000 certification |
| 8 | Investigate the food sectors currently available in Ethiopia |
| 9 | Investigate the preferred food safety certification scheme |
| 10 | Establish the number and types of food businesses – multi-nationals or local or SMMEs, etc. |
| 11 | Establish current certified status and willingness to move over |
| 12 | Establish marketing strategy to move already certified clients to the ECAE |
| 13 | Establish the importance of accredited certification and/or no need to have accredited certification |
| 14 | Develop marketing material and the marketing means for the FSMS |

| No | Action items |
|---|---|
| | certification scheme – add the relevant support services |
| 15 | Develop a certification certificate for the FSMS certification scheme, and authenticate the certificate |
| **D4** | **Laboratory services – Director – Laboratories** |
| 16 | Determine the feasibility of microbiological and food chemical testing |
| 17 | Establish programmes to support the outcome of the survey |
| 18 | Establish marketing material for the establishment of services to the food handling industry |
| 19 | Revise the scope of accreditation to include the majority of the requested tests of the food handling industry |
| **D5** | **Human resources – Human Resources** |
| 20 | No action required |
| **D6** | **Financial and liability risk assessment – Finance and supplies Director** |
| 21 | Assess the liability cover to include food safety liability |
| 22 | Determine the feasibility to be held accountable for the failure of a certified FSMS |
| 23 | Conduct a risk assessment for liability based on food safety |
| 24 | Conduct a financial risk assessment for the finances and sources of income of the FSMS certification scheme |
| 25 | Establish a means to annually review the adequacy of the liability cover for the certification activities |
| **D7** | **Legal services – Legal services** |
| 26 | Review the certification agreement to ensure it is within Ethiopian written legal requirements |
| 27 | Review the auditor or expert agreement to ensure it contains all the required information and is written within the Ethiopian legal requirements |
| **D8** | **Ethiopian food legislation – Director General** |
| 28 | Through the Director General initiate communication with the relevant role |

| No | Action items |
|---|---|
| | players for setting food legislation |
| 29 | Nominate a certification person to be a contact person or participant in addition to the role players in order to support the establishment of food legislation. This may also include the setting up of compulsory standards |
| 30 | Get copies of the relevant legislation or draft legislation |
| 31 | Evaluate the contents of the legislation against the required PRP requirements of the ISO and GMP standard and determine their feasibility for use and for auditing and implementation by organizations |
| 32 | Decide on the 'interim' decision on recommending food legislation to a certification applicant as well as the conducting of a certification with a food handler with the interim plan |
| 33 | Establish a process to have in place processes for when the food legislation is passed and becomes a legal requirement, how to communicate to certified clients, the period involved in allowing certified clients to incorporate the legislation and the certification process thereof and/or suspension of certification when non-compliance with legislation is identified after the communicated date of implementation |
| 34 | Interpret and understand the requirements and needs for food stipulated by the Federal Negarit Gazeta of 13 January 2010, Proclamation no 661/2009, and its support of other related food regulations and implications |
| 35 | Draw up the necessary criteria documents and/or checklists to support the certification process |
| 36 | Set up a training programme on the established legislation |
| 37 | Ensure that the certification personnel attend the food legislation training programme |

**Table 2:** Summary of the eight-month action item plan

| Aspect to be completed | October 2011 | | | | November 2011 | | | | | Dec 2011 | | | | January 2012 | | | | February 2012 | | | | March 2012 | | | | | April 2012 | | | | May 2012 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| **Certification personnel** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Compile a notice for the placing of an advertisement for external applicants as auditors and technical experts (and in support of the certification committee members) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Place the notice and await responses from the market place | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Evaluate applicants as well as the current internal pool of auditors in accordance with the set criteria | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Determine the pool competency and determine any required action plans should the pool not fall within the set requirements | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Communicate with the accreditation body for its acceptance and comments | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Resolve any comments made by the accreditation body by establishing a new action plan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Implement the ‘approved’ implementation plan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Certification standards, training and consulting** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Compile a request letter to the standards body for the evaluation of current GMP or PRP standards and/or setting up a specific Ethiopian | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Aspect to be completed | October 2011 | | | | November 2011 | | | | | Dec 2011 | | | | January 2012 | | | | February 2012 | | | | March 2012 | | | | | April 2012 | | | | May 2012 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| PRP standard and/or adopting an international PRP standard that would support the ISO 22000 certification activities | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nominate individuals that can follow up and participate in setting up and/or finalizing PRP related standards | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study the contents of the selected standards and compare them with the requirements for PRPs of ISO 22000 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Set up training programme based on selected standards | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ensure that certification personnel attend the training | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Ethiopian food legislation** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Determine the existence of any food legislation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nominate individuals that can participate in setting up and/or finalizing food legislation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Collect the various laws and interact with the relevant government departments to learn about the laws and their implementation etc. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study the collected laws and place them in comparison with the requirements of ISO 22000 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Set up training programmes on the collected and studied laws | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Aspect to be completed | October 2011 | | | | November 2011 | | | | | Dec 2011 | | | | January 2012 | | | | February 2012 | | | | March 2012 | | | | | April 2012 | | | | May 2012 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Ensure that certification personnel attend the training | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Certification QMS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Review the current QMS and update it to be in line with the new documentation structure and formats | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Review the generic documentation and determine the possible level of conflict of information due to changes made to documents | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Train the certification personnel and use the newly developed and updated documentation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Conduct an internal audit based on the requirements of ISO/IEC 17021 and ISO/TS 22003 in relation to the newly developed documentation and processes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Conduct a management review reflecting FSMS scheme information | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Marketing and business development** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Determine the market need for FSMS certification | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Develop the FSMS certification scheme brochure and marketing materials | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Market the FSMS certification scheme and its related services | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Aspect to be completed | October 2011 | | | | November 2011 | | | | | Dec 2011 | | | | January 2012 | | | | February 2012 | | | | March 2012 | | | | | April 2012 | | | | May 2012 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| **Finance and liability** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Determine the financial risk towards FSMS certification | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Review the current liability to include any possible FSMS certification liabilities | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Laboratories** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Determine the food handling industry's needs for food testing – Microbiology, food chemistry, nutritional value, etc. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Match the current testing activities with the market need | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Review the current scope of accreditation in order to support the newly developed scope of testing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Establish a marketing programme to market the newly included testing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Accreditation** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Communicate the final action plans required for certification personnel competency acceptance | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Officially apply for the extension of scope of accreditation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Determine an adequate accreditation assessment date | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

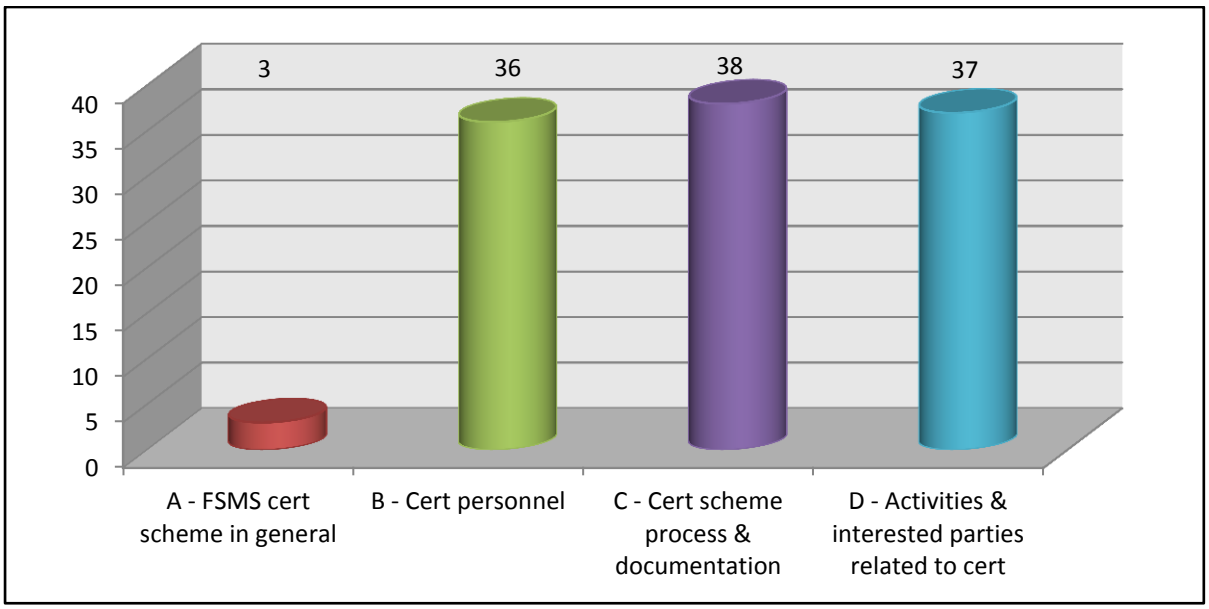


**Figure 16:** Graphic illustration of the project study 1 action item categories

## 3.5 Discussion

The inclination towards third-party certification as an independent mechanism to ensure the supply of safe food by food suppliers, retailers, food merchandisers, processors and handlers is a common feature of the ongoing economic development efforts of most countries. This has been noted in literature from various studies conducted by experts over many years. As early as 2005, Hatanaka, Bain and Busch conducted a study on third-party certification in the global agrifood system where they noted the need in shifting of the monitoring of food quality and food safety standards from a governmental or public domain to private institutions. Similar to this study, in 2014, Motarjemi and Mortimore published information on the ongoing evolvement of food safety controls through certification and therefore also the importance of inspections and audits of FSMSs where the responsibility for food safety has shifted from government to industry. Industry constantly needs to provide evidence of its knowledge of the risk associated with its food products and based on this knowledge that it is taking the necessary precautions to ensure that safe food reaches the consumer. Third-party certification became a mechanism to support this shift through the application of an objective, independent and impartial means of assessing food handling activities in the industry. Motarjemi and Mortimore (2014) explains this concept further by also reiterating the need for competencies of these third-party assessors in terms of operations of the assessment organization and application of personnel carrying out these assessments by linking them to the validity of the assessment outcome.

In Ethiopia, the Certification Directorate of the ECAE was pinpointed to be this third-party certification organization in the light of the sustainable economic development within Ethiopia in support of entering Ethiopian manufactured foods into the global market through conformity assessment activities (Hatanaka, Bain and Busch, 2005). The Certification Directorate had the benefit of already been accredited for its certification of QMSs, i.e. ISO 9001 and was therefore spearheaded to increase its capacity for certification by including FSMSs. Its accreditation implied a successful independent observation by an authoritative body on its competency to carry out management system certification audits (Sanetra and Marbán, 2007).

The organizational positioning of the Certification Directorate in relation to the NQI support revealed some challenges (Sanetra and Marbán, 2007). The first being the lack of knowledge by the certification staff on the operations of the Regulatory Framework and the legislation on food control. Other than for example with environmental management systems (ISO 14001, 2004) certification audits where a specific audit in the audit cycle will include a legal compliance audit, FSMS certification does not require that method in particular and is regarded as part of the ongoing certification audits to ensure ongoing compliance with legislation. Auditing against such requirements requires specific knowledge and skills as well as unique audit planning (Heras-Saizarbitoria, Dogui and Boral, 2013). This means that for FSMS audits compliance with legal requirements forms an integral part of the certification audit and therefore requires these skills and knowledge during every audit. The need for compliance to these requirements put pressure on the competency needs of the CB and therefore on the achievement of accreditation as competency of the FSMS auditor remains the focus of achieving accreditation. The study later on revealed, as noted in chapter one where Ayalew, Birhanu and Asrade (2013) identified various types of legislation and governmental departments were available and active at the time of the study period although it was not known by the ECAE personnel. The presence of legislation therefore indicating that a Regulatory Framework was already in place and this was seen as a positive point in moving forward with FSMS certification. The extent of applicability, completion and/or wholeness in terms of functional legislative support for food safety was however not determined.

A second challenge noted from the study was that the NAB was still in the process of being developed and would most probably not be able to conduct the accreditation assessments of the Certification Directorate. This implied that an external body (cross-border accreditation support) had to be used and was therefore regarded as a financial burden towards sustaining the FSMS certification scheme even though multilateral recognition agreements between such bodies had been set up to support the facilitation of acceptance of accredited certification (Steyn, 2010).

Certification is the concept of confirmation of the conformity to requirements of standards, whether national, international or private, and the role of standards is

therefore fundamental in this process (Sanetra and Marbán, 2007). A positive point therefore was that the NSB was established and operational and could therefore play a supporting role towards certification. Knowledge on and the availability of the supporting standards for ISO 22000 were, however, found to be lacking. The difficulty in the purchasing of the relevant standards was identified as a stumbling block towards the successful implementation of ISO 22000 and food safety as a whole. The absence and/or difficulty in obtaining these standards due to the difficulty in attaining them were therefore regarded as problematic and was seen to may have a negative impact on the effective operations of food facilities, activities of food handlers, training and consulting activities as well as the certification of FSMSs.

Knowledge of the requirement needs and relevance of food safety certification schemes in Ethiopia and possibly even the differences between them was very limited in terms of the certification client. It is common knowledge that the customer sets requirements and expectations for products or services and this phenomenon is no different to food safety. A retailer as a customer, for example will set the preferred standard for the operation of an FSMS and its certification as part of their purchasing requirements and in order to mitigate risks to their business by ensuring consumer protection (Sanetra and Marbán, 2007; Kleemann, Abdulai and Buss, 2014). The certification personnel knew about ISO 22000 as a FSMS certification scheme supposedly because they were obliged to follow through with the implementation of the ISO 22000 based food safety certification scheme because it was part of the sponsored capacity building project and most likely because it is a common certification entrance scheme into the market place globally. ISO 22000 is commonly regarded as ‘the’ International Standard for food safety and it is often presumed by sponsor organizations supporting the development of a NQI that it is the ‘accepted’ standard to apply for certification in a global market place where trading of goods is based on a typical ‘ISO’ relevant standard requirement. This is normally the foundation for international standardization and the basic acceptance criteria required to trade goods in accordance with the agreements under the WTO noted in chapter two. This typical food safety monitoring methodology is further supported through a study done by Jongwanich (2009) and Neeliah and Goburdhun (2010) indicating its commonality within the market place.

Market knowledge of the needs for FSMS certification, entrance into the market, marketing strategies and exposure of the certification brand of ECAE had not yet been attended to. Meeting market needs meant that the preferred certification scheme and/or schemes would set the tone for the operations of the Certification Directorate and its accreditation. The need for knowledge of the market needs for certification was also illustrated by the study done on third-party certification by Hatanaka, Bain and Busch in 2005. The sustainability of the FSMS certification scheme and therefore the impact of the Certification Directorate of the ECAE within the NQI framework depends on the needs of the market and it was therefore crucial for the ECAE to gain knowledge of the market needs of the industry relevant to food manufacturing and most probably Government priority for economic development through food. The ECAE had to be sensitized to take cognizance of the relevance of the international attention to food safety and food safety standards in international trade and their ongoing change and adaption to market needs and needs to ensure consumer safety (Unnevehr, 2015). ISO 22000 based FSMS certification was certainly not the only or most prominent FSMS certification scheme in the market.

The presence of multinational food handling organizations in the country may have been in a better position than the local food handling organizations to comply with the FSMS requirements as their 'headquarters' organizational requirements are set up in countries by individuals who have had exposure to such requirements and have the resources for the development of the FSMS to achieve certification. The certification scheme of these multinationals could also be schemes other than those based on ISO 22000, something that was not investigated by the Certification Directorate personnel and/or marketing personnel as these facilities may be able to support the Certification Directorate with capacity building towards their FSMS certification scheme.

Surprisingly then, the lack of knowledge of the importance of food safety in general, not to mention its certification, was reiterated by the noticeable lack of preparedness and implementation of food safety as recommended by ISO 22000 in the facilities visited during the study period owing to the level of their compliance with food safety standards. The sample taken in terms of the food facilities visited was by no means a true reflection of the overall readiness of Ethiopian food facilities for FSMS

certification, however, those visited indicated that more exposure to food safety, and especially HACCP, is required. The time however allocated to facility visits did not allow for a full audit exercise to demonstrate the activities of a typical ISO 22000 audit which had to include all the on-site audit activities required by the standard and methodologies as discussed in the study done by Motarjemi and Mortimore (2014), namely an opening meeting, collecting of audit evidence in accordance with the audit plan, audit conclusion determination, and the closing meeting. Time was spent to expose the audit team to specific aspects of food safety and the auditing of food safety processes. The questions asked and the type of explanations required by the audit team for the application of some of these audit activites and the use of the necessary audit process documentation during the facility visit reflected the need for them to have more exposure in the conducting of ISO 22000 audits and/or at least be supported by someone already knowledgeable in these types of audits in assisting them to build their own knowledge and skills as food safety auditors. ISO 22000 was not the only FSMS applied by the facilities visited, which again reiterates the need for knowledge on the market needs as well as the different standards and their application. A more detailed look at food safety during the facility visits from the point of view of the Certification Directorate revealed a few concerns for the audit team: (i) ISO 22000 certified facilities indicating non-compliance with the basic PRP requirements versus the non-certified facility indicating compliance with these PRPs, (ii) the difficulty and, in some respects, the incorrect application of HACCP in relation to the requirements of ISO 22000, (iii) the comparison of management systems between the consultant-supported facilities and their similarities of compliance and non-compliance, versus the non-consultant-supported facility indicating a more acceptable level of compliance, (iv) the certification difficulties experienced by the certified facilities, and (v) the possible difficulties in taking over certification in order to penetrate a market that is already convinced that non-Ethiopian CBs are preferable.

The problem with FSMS certification was therefore twofold in terms of the certification body and the facilities, namely in their auditing knowledge, certification scheme knowledge and the implementation knowledge by facilities. The resolution to these problems needed further planning and execution by both the industry and the Certification Directorate. For the Directorate, reaching competency of the auditor

pool as food safety auditors remained a major focus of the accreditation of the Certification Directorate. Facilities on the other hand may need additional support to reach compliance with food safety requirements and its certification expectations.

The development and presentation of ISO 22000 training course by the Training and Technical Support Directorate was regarded as a supporting service in assisting not only the industry with information on food safety but also the certification personnel. The course did not, however, include sufficient detail with regard to Ethiopian specific standards and legislation. Nor did it give enough attention to the scientific foundation of HACCP and the application of HACCP methodologies in relation to ISO 22000 versus general CODEX-based standards or documents. These aspects needed to be corrected for the Ethiopian food industry to meet the requirements of best international practice and therefore also compliance with ISO 22000 in particular. This was after all the underpinning focus of the FSMS certification scheme.

Additional supporting services to certification clients such as the testing of food materials were found to be operational and accessible on the premises of the ECAE, however, laboratories did not place their focus on supporting the industry with food safety hazard testing. The cost of setting up, running and maintaining testing facilities on sites of food handling organizations makes it unfeasible for them as well and poses a risk of contamination, for example with the testing of pathogens, and it is therefore more sensible to make use of centralized laboratories, privately owned or government owned to run the number of tests required to support food safety (Sanetra and Marbán, 2007). In the case of the ECAE, which did have a set of laboratories covering the range of possible food safety hazard testing, the coordination of capacity building projects between certification and the laboratories of the ECAE could have been better coordinated by the sponsor organization in terms of the ECAE's service support to the industry. These laboratories had limited knowledge of food safety hazard testing needs of the industry. In the study conducted in 2005 by the FAO/WHO, the availability of competent laboratories was identified as a need for the functional operation of various activities within Ethiopia, including food control. The ECAE was in a position through this capacity building

programme to meet these needs, however, activities of the project and the operations of ECAE was not applied to satisfy this need.

The management structure of the Certification Directorate was found to be suitable and active in the management of all the required conformity assessment activities. The interaction and communication between the organizational and Certification Directorate quality managers needed improvement in support of the overall concepts of QMSs within an organization. Certification processes were also seen to be suitable, however, it was noted that they have been established for the ISO 9001 (QMS) certification scheme and the focus of operations remained in line with typical ISO 9001 requirements. These certification processes could also be used for the ISO 22000 (FSMS) certification scheme but had to be adapted to incorporate food safety specific requirements and possible unique auditing activities and auditor competency requirements. What was regarded as a positive point was that the set format and order of carrying out the certification processes were already entrenched in the certification personnel and this could be used to build the FSMS certification processes (Motarjemi and Mortimore, 2014).

Part of this management structure and based on the requirements of QMSs in general, the Certification Directorate had appointed a quality manager who had to oversee the operations and maintenance of the QMS for the certification schemes. What was surprising though was his workload that was seen to be rather overwhelming as it included all the certification activities of the Directorate and was therefore not specifically focused to support management system certification. He was in a way disempowered by personnel of the Directorate based on their long-standing involvement in management system certification over the years leading to a belief that a single nominated quality manager for management systems certification was not required. The quality manager had also not received training on the ISO/IEC 17021, ISO/TS 22003 and/or food safety requirements and therefore found it difficult to support the overall development and implementation of the FSMS certification scheme. This situation indicated that the sustainability of the QMS for the Directorate over time will be influenced negatively as the maintenance of the QMS, including the accreditation, will be jeopardised. A more focused arrangement for the development, implementation, management and maintenance of the QMS by the quality manager

had to be reconsidered. This would also have supported the focus towards the FSMS certification implementation activities as a single ‘project owner’, something that was not noted and therefore not operational which led to the scattering of project work and decision-making.

Operationally further, in terms of the application review process of certification personnel for the FSMS certification scheme, the certification personnel were found to be compliant with two-thirds of their requirements set out in ISO/TS 22003 (2007). This was better in comparison with the certification decision-making personnel who reflected mostly a lack of compliance with the requirements of ISO/TS 22003 (2007). The latter observation was particularly concerning because the decision for certification is derived from the certification decision committee and forms an integral part of the competency criteria for the accreditation process. This concern was then extended to the auditing personnel where it was found that although there was an extensive auditor pool, very few of them could qualify for conducting food safety audits. The biggest dilemma was the personnel’s work experience, in some cases their education and then the combination of lapsed training and lack of training on ISO 22000, its understanding and application in an audit situation. The dilemma further included the lack of knowledge of standards (other than ISO 22000) and legislation that, in some cases were applied by audit clients and thus had to be taken into consideration during the audit processes of ISO 22000.

It became obvious during the gap analysis phase that the auditing personnel required exposure to ISO 22000 in food facilities in order to experience the various interpretations and applications of the standard. In a study carried out by Heras-Saizarbitoria, Dogui and Boiral (2013) where they indicated that the certification standard leaves a lot of scope for interpretation of its requirements by auditors, it is inevitable that auditors will then do so, and focus had to therefore be placed on assisting auditors with training on ISO 22000 in terms of understanding of its application and its auditing. The building of capacity, adding of knowledge to the auditing processes, and access to auditing personnel external to the organization were options but meant that additional requirements towards protection of the integrity of the auditing processes and activities within the QMS had to be considered and developed. Ultimately, the success of an audit is based on the

competencies of the audit team and this again is based on the level of knowledge, skills, education and particular industry and auditing competencies of the individuals of the team who are able to apply all of these competencies in a practical and effective manner during an audit (Motarjemi and Mortimore, 2014).

During the documentation review part of the gap analysis it was revealed that the certification personnel only considered looking at the needs for documents required for the on-site certification activities of the FSMS certification scheme. Very little to no interaction with the rest of the QMS documentation could be seen even though it was expected of the certification personnel to have considered the interaction of the QMS with both certification schemes, i.e. ISO 9001 and ISO 22000, purely because of the shared generic requirements of the ISO/IEC 17021 (2011) standard. The additional requirements of ISO/TS 22003 (2007) were considered but also as the minimum and was therefore also be seen to have been dealt with in a limited way. This therefore resulted in the development of sporadic documents within the QMS which was seen to be problematic in terms of achieving accreditation for the FSMS certification scheme.

Certification personnel who were responsible for the establishment of the FSMS certification documentations also believed that the QMS already complied with the requirements of ISO/IEC 17021 and therefore did not review it fully for its compatibility and inclusion of the FSMS certification requirements. The lack of knowledge of the compatibility and even similarities between QMS and FSMS certification scheme documents in relation to the QMS stifled the development of the FSMS certification scheme. These personnel also did not want to deviate too much from the structure and format of the QMS and this made the inclusion of the FSMS certification documents difficult to fit into the QMS leading it to be complex, user-unfriendly and therefore difficult to work with. The adding of information to documents, as well as the establishment of new documents for the QMS were found either to contain direct text from the standards or was written in a direct translated form of English which in the interpretation of the written text altered the meaning of the application of the activities and/or indicated deviations from the actual requirements of the standards. Convincing personnel during the review to alter the contents of documents to make them more correct and accurate in terms of

language and the compliance with the requirements of the standards was not always welcomed or accepted. This together with the format problems noted during the review indicated stagnation in the establishment and completion of the FSMS certification scheme.

In theory then, the QMS documentation for the FSMS certification scheme was developed but not yet applied in an auditing situation, and especially not against ISO 22000. This scenario and results of the review indicated a negative impact towards achieving accreditation as the competency of the certification personnel could not yet be demonstrated in terms of the application of the QMS. A vast amount of work had to be conducted to ensure compliance with the requirements of the standards where competency requirements were stated, and this included ISO/IEC 17021 (2011), ISO/TS 22003 (2007) and ISO 19011 (2011).

The human resources aspect of the Directorate as a supporting function were very much supportive of the processes required to assist the Directorate with the appointment of suitable certification personnel as well as their continued building of knowledge and skills. Although they were not knowledgeable on the specific certification personnel requirements, the communication between the two areas seemed to be active and supportive of the process. It would, however, be more effective if the Certification Directorate informed them generally about the certification personnel requirements as this would lessen the burden of also ensuring compliance with specific and in some cases very technical requirements regarding personnel competency.

The legal services department, also as a supporting function to the Directorate played an important role in the certification activities in that they oversee the management of certification related agreements. Incorporation of the ISO/IEC 17021 and ISO/TS 22003 specific requirements relating to the certification agreement, some certification activities and agreements relevant to the use of external auditors and technical experts had to be upgraded to ensure full compliance with the two noted standards.

Like the legal services department, the finance department had to support the Certification Directorate with aspects of financial risk assessment and the supply of a relevant and suitable liability cover. The FSMS certification scheme activities had to still be included in this risk assessment as well as the liability cover. Coordination between the legal services department and the financial department was also required where the legal services department needed to advise the finance department on the possibility to be held liable for certification activity failures, i.e. food-borne disease caused by a FSMS certified facility, and therefore in that way support them with the establishment of the level of liability cover to be attained. It was not clear from Ethiopian legislation if the ECAE can be held liable for certification failures since the organization was Government derived and forms part of an integral part of the NQI framework.

Lastly, a two-day orientation session was conducted which was an extension of an introductory training session conducted for the ECAE personnel. The two-day session included internal personnel as well as external people representing interested parties towards FSMS certification. Various points regarding food safety, such as ISO 22000 and legislation were included in the discussions. In conclusion of this two-day session as well as the introductory session it was clear that more training sessions on this subject had to be conducted. Knowledge of food safety and ISO 22000 was certainly needed, not only for the industry, interested parties, but also for the personnel of the ECAE.

### 3.6 Conclusion

A QMS for the conducting of management system certification activities was in place at the Certification Directorate of the ECAE, and has been accredited against best international practices, i.e. ISO/IEC 17021 (2011), for some time. The extension of the scope of its accreditation towards the certification of FSMS led to the identification of the needs for specific changes and improvements in its QMS and execution of certification activities. The results obtained from the gap analysis on the shortcomings of the Directorate after its own attempt to deal with its needs for the extension of the scope resulted in the identification of various aspects that had not yet been dealt with, had in some way been attended to or needed improvement. The extent of the gap identified that the Certification Directorate may not yet have

realized the full extent of the needs required to reach the goal of achieving an extended scope accreditation. The identified gaps led to the creation of an action item list of 114 activities. These activities were spread out over the range of requirements of the certification scheme in general, certification personnel, processes and documentation and also activities of relevant interested parties and role players of a certification process. Personnel were tasked to action these items noted in the action item list over eight months.

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# CHAPTER 4

# CAPACITY BUILDING INTERVENTIONS FOR THE ETHIOPIAN CONFORMITY ASSESSMENT ENTERPRISE: A COMPARATIVE-PROGRESSIVE ASSESSMENT

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## 4.1 Introduction

The GIZ under the auspices of the NQI Project of the National Growth and Transformation Plan in Ethiopia required additional assistance in the field of conformity assessment towards the development of a food safety management system (FSMS) certification scheme that could become accredited once implemented. The overall objective of the NQI Project in Ethiopia was to build capacity towards the Ethiopia NQI thereby improving the competitiveness of manufacturing and service providing enterprises in line with international best practices. Transformation of the ECAE towards international best practices in terms of conformity assessment was one of the key result areas of the GIZ NQI capacity building project in Ethiopia. The ECAE provided conformity assessment services in the areas of product testing, inspections and certification. Accredited certification systems had to be delivered in order to build trust and competitiveness not only in the local industry, but also internationally as a global trading partner.

The results of the study 1 capacity building project indicated various obstacles to the application of the FSMS certification activities within the ECAE. These obstacles were hindering the completion of the implementation process and therefore also the accreditation of the FSMS certification scheme as an overall outcome of the capacity building project.

A second capacity building project was introduced two years after the initial project at the ECAE under the management of the GIZ with the aim of continuing the support of ECAE in the development and implementation of a QMS to manage the FSMS certification scheme which had to be accredited against best international practices. The objectives of this study were:

a. providing advice to the Certification Directorate of the ECAE on the processes required for the developing, implementing and maintaining an FSMS certification scheme benchmarked against international best practices and application of harmonized assessment procedures;
b. establishing an effective certification policy and strategy;
c. devising a mechanism of ensuring close corporation with various regulators and other NQI institutions;

d. reviewing the adequacy of the established FSMS certification scheme drafted documents and assisting in establishing the missing documents;
e. assisting in establishing certification personnel competence for the scheme through the development of appropriate selection criteria for personnel with respect to educational qualification, industrial and work experience as well as audit experience relevant to the required accreditation food chain categories C, E and G reflected in ISO/TS 22003 (2007);
f. conducting a factory assessment audit and proposal of corrective actions to be taken by the factory. Relevant audit documents for the factory assessment had to be developed;
g. developing and delivering progress reports, proposals, required documentation and presentations periodically to the management of the ECAE and the project;
h. developing documentation and a management system manual in line with ISO/IEC 17021 (2011), ISO/TS 22003 (2007), ISO 22000 and the accreditation body requirements;
i. organizing and presenting a workshop on the management system documentation developed and on the overall FSMS certification scheme methodologies; and
j. writing a summary report of the accomplished activities of this capacity building project and the programme.

## 4.2 Materials and methods

The materials applied to this comparative progress study included the set of work procedures of the ECAE established during the study 1 capacity building project and the mandatory international standards and supporting documents applied for establishing, implementing and maintaining an accredited food safety management system certification scheme. As a minimum for this project, reference had to be made to ISO/IEC 17021 (2011) and ISO/TS 22003 (2007) as the foundation requirements to a food safety management system certification scheme. Further mandatory and voluntary requirements would be information supplied by the IAF and the selected accreditation body in terms of their specific or additional requirements. The supporting information would then be what the scheme intends to certify against, which in this case was ISO 22000 (2005) and ISO/TS 22002-1 (2009).

The methods applied to this study were based on the outcome of the gap analysis methodology applied and the assessment of the progress made towards achieving an accredited FSMS certification scheme status. Capacity building needs in the format of training sessions and recommendations had to be applied. The progress assessment methodologies were based on the application of seven activities as follows:

- Activity 1 (Objective a, g, j): A progress assessment of the submitted study 1 action item list in relation to the recommended and approved timelines for its completion.

The study 1 capacity building project concluded with the establishment of an action item list detailing the required action items that had to be conducted to ensure that the FSMS certification scheme is implemented and that progress is made towards a positive accreditation outcome within a defined period. This action item list was used as the first comparative progress study document for the purpose of measuring the progress made with the overall capacity building project.

The action item list, noted in Table 1 was drawn up to include four major areas of activity, which remained the framework for the comparative progress study. These areas of activity included:

a. A – Food safety management system certification scheme in general
b. B – Certification personnel
c. C – Certification scheme process and documentation
d. D – Activities and interested parties related to certification

- Activity 2 (Objective b, d, h): A document review to assess the progress made with the development and implementation of documents noted from the study 1 capacity building project required for the completion of the FSMS certification scheme management system processes required by the mandatory international standards and supporting documents.

This review had to also include an overall review of the design of the QMS of the Certification Directorate. The QMS had to reflect the various levels of documents in support of the different functions within the management of certification activities, for example:

a. management system manual;
b. policies;
c. management system activities;
d. certification processes in general and then specific to a particular certification scheme;
e. certification personnel processes; and
f. legal documents.

The review was based on the criteria stipulated in Annexures 3.1, 3.2 and 3.5.

- Activity 3 (Objective e): A certification personnel review to assess the progress made with the identification, training and application of competent food safety certification personnel noted from the study 1 capacity building project.

Certification personnel that had to be included in the review included the following:

a. application reviewers;
b. certification decision makers;
c. an impartiality committee;
d. auditing personnel; and
e. technical experts.

The review was conducted against the criteria stipulated in Figures 4, 5 and 7 and Annexures 3.3, 3.4, 3.5 and 3.6.

Competencies had to be determined for the selected food chain categories as noted in Annexure 3.5. Particular focus had to be placed on the following categories:

a. C – Processing 1 (Perishable animal products) including all activities after farming, i.e. slaughtering
b. E – Processing 3 (Products with long shelf life at ambient temperature)
c. G – Catering

- Activity 4 (Objective f): A review of a food facility in support of establishing the readiness of the food industry for FSMS certification and to review the practical application of the developed documentation required for food safety certification audits.

A food facility willing to participate in the capacity building project had to be nominated and a typical certification audit conducted. The certification process reflected in Figure 8 had to be applied during the review process in order to reflect the actual implementation of an FSMS by the facility and practical application of the developed certification processes applied by the auditors. The nominated food facility had to be ready for certification against the ISO 22000 (2005) and ISO/TS 22002-1 (2009) standards. The on-site activities would also be applied to assess competencies of the auditing personnel. On-site evaluation of auditing personnel is also a requirement of the ISO/IEC 17021 (2011) standard and would therefore act a dual purpose in that not only the evaluation of competencies of the auditing personnel but also providing evidence of an evaluation process required for accreditation. Annexure 3.7 would also be applied during this review.

- Activity 5 (Objective c): A review of the progress made with the incorporation and coordination of support by NQI institutions towards the application of the FSMS certification scheme in Ethiopia.

The study 1 action item list in terms of relevance of the NQI institutions had to be applied for this review.

- Activity 6 (Objective i): Organize and present a workshop on the QMS documentation developed and the overall FSMS certification scheme methodologies.

This workshop had to be based on the completed QMS that was developed during the full capacity building project period time, therefore study 1 and study 2.

- Activity 7 (In addition to the objectives): A ToR comparison of the two capacity building project study periods as an overall review of the impact of ToR towards the effectiveness of capacity building projects based on donor organization interventions in support of the programme summary report.

The study 1 ToR was compared with the study 2 ToR as a final output to the comparative progress study.

## 4.3 Results

### 4.3.1 Activity 1: Study 1 action item list comparative progress assessment

At the start of the activity of the comparative progress assessment of the study 1 action item list noted in Table 1 it was discovered that the action item list was never communicated to the relevant certification personnel. Very little to no actions in accordance with the action item list had therefore been executed in the period between study 1 and study 2. Certification-related activities that had been actioned by the certification personnel from the time of the study 1 capacity building project was applied based on their knowledge obtained during the study 1 project and the knowledge obtained through the practical application of auditing methods used during their normal work programme executions. The action item list was not applied to engage in any progress made towards the completion of the FSMS certification scheme based on the recommendations made through the capacity building project.

Annexure 4.1 reflects the details of the action item list where the recording of the results as ‘no action taken (red)’, ‘action taken but to be completed (orange)’, and ‘action completed (green)’ were noted during the comparative progress assessment. The results of the comparison between the two study periods are indicated by Figure 17 and it reflects that more than 80% of the action item list had not been dealt with and/or actioned. This result impacted negatively towards the execution of the other noted activities and then overall on the objectives for this study period. The capacity building project in theory could therefore not move forward.

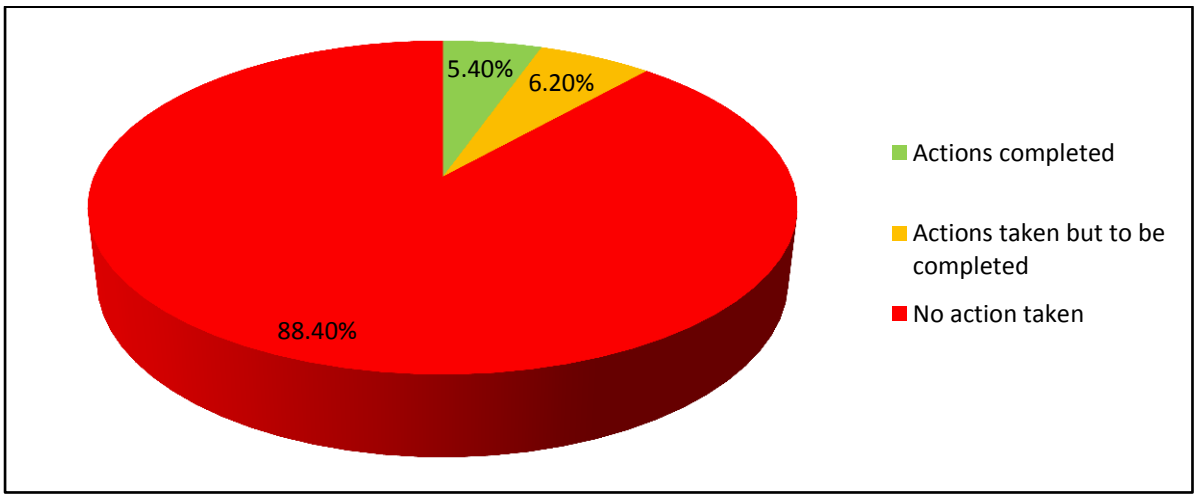


**Figure 17:** Illustration of the summarized comparative progress assessment result

In the absence of sufficient progress made with the study 1 action item list, a decision was taken to assess supplementary results through gathering additional information on the development and implementation of the FSMS certification scheme through discussions and the assessment of various other relevant data that were of particular importance and applicability to this capacity building project. Table 3 indicates the supplementary results gathered in support of the action item categories noted during the study 1 period which were based on the four main categories noted during study period 1. These four categories are illustrated in Figure 15.

The results noted in Table 3 were added to the recommendations made as part of the output of the study 2 action item list reflected in Table 7, and although necessary in support of achieving the overall goal for the FSMS certification scheme, i.e. its accreditation, they now added to the burden of completing actions from an action item list comprising two study periods. No specific progression action item list could be developed for this second study period which had to focus on the next phase of implementation activities towards the completion of the FSMS certification scheme. Cognizance was also taken of some items noted on the study 1 action item list as being of a high level and required intervention by stakeholders of the Certification Directorate. These items could not be completed during the study 2 capacity building project and therefore remained as ‘not actioned’ on the action item list.

### 4.3.2 Activity 2: Documentation review

The QMS of the ECAE had an accredited status during the study 1 period when the initial capacity building project was implemented and continued to be accredited against ISO/IEC 17021 at the time of the second capacity building project period. An accreditation surveillance assessment was conducted in between the two study periods by a German accreditation body. The surveillance assessment was conducted against the 2011 version of ISO/IEC 17021. The ECAE had then applied for the extension scope of their accredited QMS towards QMS certification as well as for the inclusion of FSMS and environmental management system certification schemes. The scopes of the FSMS certification scheme applied for included the food chain category C, processing of meat, poultry, eggs, dairy and fish products,

**Table 3:** Summary of supplementary assessment results in support of the capacity building project

| Related category | Supplementary result |
|---|---|
| – | There was a change in the position of Quality Manager since the study 1 period. The newly nominated Quality Manager had not been exposed to the FSMS certification activities and had also not yet received all his responsibilities relating to his appointment.<br>He had also not yet been given access to the soft copies of the QMS documentation.<br>The study 1 period Quality Manager in terms of his position was identified to be a member of the application review committee and therefore played in integral role in the certification process.<br>The newly nominated Quality Manager was, however, not able to fulfil this particular role which then placed a burden on the FSMS certification scheme in terms of the functionality of the application review process. |
| | No further development took place in terms of the QMS of the organization overall, and then in particular of the links to the different Directorates. |
| A | An FSMS certification scheme specific coordinator had not yet been identified after the study 1 period. This led to the non-actioning of the action item list.<br>Work conducted between the study 1 and study 2 periods was managed on an ad hoc basis by the certification personnel of the Certification Directorate and was mostly carried out by one individual and supported by two other individuals from time to time.<br>These individuals did not in particular reflect the required food safety criteria stipulated by the ISO/TS 22003 requirements.<br>The food safety certification scheme development could therefore not move forward to reach an accredited status. |

| Related category | Supplementary result |
|---|---|
| B | No progress was made towards building capacity in terms of FSMS certification personnel.<br>Advertisements for auditing personnel were placed in the local newspapers, however, no suitable candidates could be appointed and/or subcontracted in support of the certification activities.<br>Arrangements for the use of personnel from another CB took place, however, this was not actioned. |
| | Not all relevant information on the contents of qualifications that may be relevant to food safety certification had been collected.<br>It was therefore not yet known which qualifications in terms of the education of certification personnel will be suitable to reflect compliance with the requirements of ISO/TS 22003. |
| C | FSMS certification activities were not included in the impartiality committee meetings, management review activities and internal audit processes. |
| | Marketing material had not yet reflected the services of the ECAE in terms of food safety.<br>Knowledge of other food safety certification schemes and market needs was not gained. |
| | Certification certificates did not yet reflect the recommendations made to secure their authenticity.<br>Food safety certification certificates were not developed. |
| | The majority of documents assessed during the review indicated that very little reviews and updates had been made.<br>Documents were still reflecting the 2006 version of ISO/IEC 17021.<br>Work on the QMS documentation towards the certification schemes, being quality and/or food safety had not yet moved forward.<br>Nearly 31% of documents of the QMS required review and updating. |
| D | Some work had been done on the financial shortcomings in terms of external auditing personnel as well as certification fees.<br>The results of discussions were not implemented. |

| Related category | Supplementary result |
|---|---|
| | No further knowledge was gained on food safety certification needs of the industry.<br>No market relevance in terms of food safety had been collected. |
| | The request during the study period 1 put forward to the Standards Agency regarding standards was not actioned.<br>ISO standards could not yet be purchased by the public.<br>Other relevant FSMS certification standards had not yet been identified and could therefore not be adopted, revised and/or developed. |
| | The correctness and accuracy of the training and consulting activities provided by the Standards Agency could not yet be determined as presentation of courses and consulting activities mostly remained towards ISO 9001.<br>Food safety in terms of ISO 22000 judgements could not yet be made owing to the lack of food safety specific knowledge and experience of personnel. |
| | No knowledge was gained on the other relevant supporting services to FSMS certification, i.e. food testing, microbiology testing, etc.<br>The interactions between the services provided to the food industry by the organization were therefore not known and seen as being inactive. |
| | Personnel in general were employed based on a scientific qualification, however, they were sometimes employed in areas not matching their qualifications, i.e. a person with a food-related qualification was employed in the chemistry laboratory.<br>Not much work had been carried out to ensure that the correct persons are appointed and match the required needs of the area or position.<br>This impacted negatively towards FSMS certification personnel as they could then not be matched to the food chain categories and/or scope sector codes on which certification operates.<br>These personnel employment and placement issues also impacted negatively on the morale of personnel as they were being applied in areas where their qualifications could not support their work.<br>Career planning and continual professional development will be stifled |

| Related category | Supplementary result |
|---|---|
| | and the organization will be placed under immense resources pressures as the reliance on external personnel rather than internal capacity building will become a reality. |
| | A financial risk assessment was not conducted to include FSMS certification activities.<br>It was also not clear if the liability cover would be sufficient to include possible FSMS certification liabilities. |

category E, processing of canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, and salt, and category G, catering in terms of hotels and restaurants. The extension of scope accreditation assessment was planned for the middle of the year during the study 2 period implying that all relevant work towards the completion and implementation of the FSMS certification scheme QMS documentation and processes had to be completed in a short period.

The study 1 capacity building project was concluded with 41 applicable documents towards the FSMS certification scheme. Some of these documents were also applied to the QMS scheme and were therefore seen as the general QMS foundation documents supplemented with food safety specific technical documents.

The study 2 period document review phase revealed that the documents developed during the study 1 period had not yet been applied within the QMS and/or during FSMS certification activities. Their finalization and approval also had not yet been completed. It was further established during the review that the full QMS contained about 106 documents and that these documents played a fundamental role in the foundation of the FSMS certification scheme. The 106 documents found during the study 2 period excluded the FSMS certification documents established during the study 1 period. The full set of QMS documents was therefore never assessed or considered during the study 1 period and this impacted negatively on the comparative progress review that had to be conducted during the study 2 period. A full assessment of the QMS documentation had to then be conducted before the actual progress review could take place. This stifled the capacity building project towards the assessment, identification of any gaps and possible development and/or improvements of documents as part of the project. The project time did not allow for time to be allocated to this. The completion of documentation of the QMS did therefore not move forward and no improvements towards the certification processes in line with international best practices could be achieved.

The review of a bigger sample of the QMS documentation revealed that a number of documents could be seen to be common between the different management system certification schemes. The review also revealed that in certain cases, scheme specific documents had to be established owing to the uniqueness of the application

of the specific certification standard, such as ISO 9001 or ISO 22000 or ISO 14001. During the assessment 33 QMS documents were identified as possible common documents that may also be applied to food safety certification, however, these documents required a deeper level of review which could not be completed during the study 2 period. Of the 33 identified documents, 12 were reviewed, eight were corrected or completed for the purpose of supporting FSMS certification and 12 remained unreviewed. A document required for the peer review of auditors was in particular identified as being required for FSMS certification and attention was placed on this document to have it completed in order to move forward in achieving accreditation.

The study 1 period revealed that the overall design of the QMS was suitable for the application of one certification scheme, i.e. QMS. This QMS reflected the levels of documents illustrated by Figure 18.

These QMS documents further reflected a typical method for the development of a management system, commonly not through thought in terms of its planning, numbering and placement within the system but rather sequentially as they are developed and/or needed. This, over a period created a long list of documents without any order leaving only the document developer familiar and comfortable with the QMS set-up and documentation. Users of the QMS then struggled to find and apply documents. The lack of proper planning impacted negatively on the use of documents of the management system and also on maintaining the documentation of the system.

The study 1 intervention also reviewed the QMS design to support the certification of more than one certification scheme. The introduction of additional management system certification schemes generally complicates the management system design based on the various types of documents required, and, subsequently the identification and numbering of documents within the management system. As an output of the study 1 period a recommendation was made to consider the QMS design in terms of the levels of documents illustrated by Figure 19.

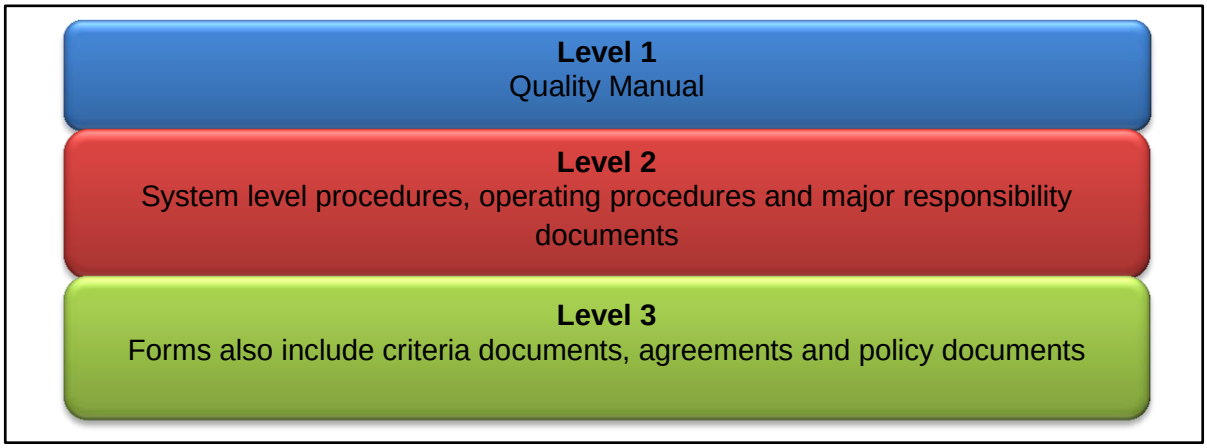


**Figure 18:** Schematic illustration of the levels of documents presented by the QMS design

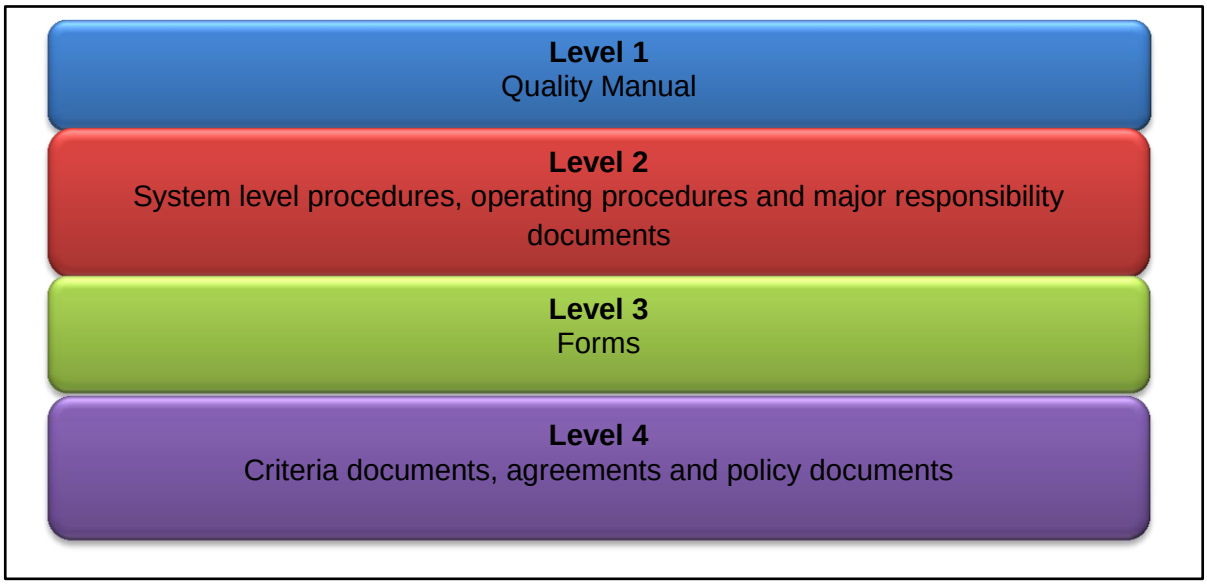


**Figure 19:** Schematic illustration of the recommended levels of documents within the QMS design

The reviews conducted during the study 2 period revealed that the QMS design had not been reviewed and updated as recommend during the study 1 period. The QMS then had to during the study 2 period and as part of the overall capacity building project be redesigned in order to support the functionality of it to provide for the extension of scope of work and accreditation of the Certification Directorate. This was required to support the ongoing inclusion of the additional certification schemes and to ensure that the ongoing documentation development process is therefore of a planned and structured way. The recommendations for a more structured design of the QMS were made and incorporated the levels of documents illustrated by Figure 20.

The documentation design in terms of its numbering was then further supported by recommending including the abbreviation of the document level type, noted for example in brackets in Figure 20, as well as then to file them in an orderly numbering way in accordance with the levels. The level 7 documents would further be supported by additional abbreviations for the identification of the specific scheme, such as a ‘Q’ for QMS, an ‘FS’ for food safety, an ‘E’ for environment, and an ‘O’ for occupational health and safety. An example illustrating the recommendations was set up for the certification personnel through the development of a document list and is illustrated by Figure 21.

The QMS had to be reorganized to reflect the recommendations made towards the design and set-up of documents within the system. This had to be completed by the certification personnel who participated in the project after the project period. A proposed document list was drawn up as an outcome of the documentation review and redesign of the QMS and was to be applied as a guidance document in completing the certification QMS with the inclusions of all relevant certification schemes.


**Figure 20:** Schematic illustration of the recommended structured design of the QMS

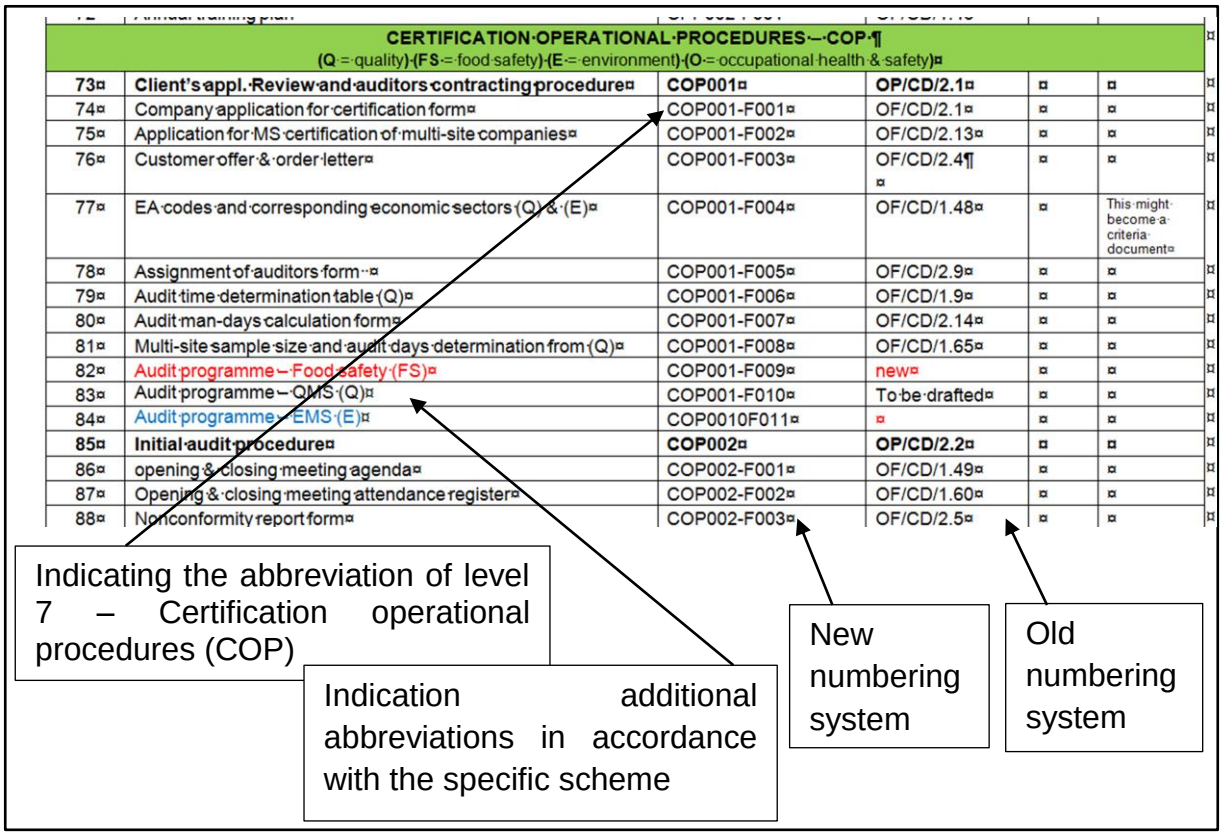


**Figure 21:** Recommended documentation numbering and filing in accordance with the recommended structure design

### 4.3.3 Activity 3: Certification personnel review

Other than the Quality Manager, the certification personnel participating in the study 1 period remained the same for the study 2 period.

The functions of the Quality Manager are to ensure that the QMS of the CB is established and maintained, especially when accreditation plays a role. The review of the QMS further revealed that the new Quality Manager had already been appointed during the study 1 period, however, he had not up to the study 2 review period been given clear instructions on his responsibilities and authorities and had also not yet been given full and free access to the QMS documentation. This Quality Manager was also active in the activities of the product certification schemes in terms of management system controls and technical expert work. His participation in taking the FSMS certification scheme forward was therefore limited and this stifled the progress expected to have been made by the study 2 period, including the planned accreditation assessments aimed at for mid-year.

Advertisements for the appointment and/or contractual arrangements for auditing personnel and technical experts were placed in the local newspapers late during the study 1 period and then again early the following year. Only six applications were received during the first attempt and none during the second attempt. On reviewing the applications, Table 4 reflects the results found:

The review of these applicants in relation to Annexures 3.3, 3.4, 3.5 and 3.6 revealed that they did not reflect compliance with all the relevant criteria set out for FSMS certification auditing. No further work was conducted by the certification personnel to support the building of capacity towards the FSMS certification scheme. The option for supporting these applicants with filling the gap through for example, training, additional education, work experience, and the support of a technical expert to bridge the gap, towards their auditor training and experience was also not considered.

**Table 4:** Results of the reviewed certification personnel applications for study 1

| | |
|---|---|
| Types of qualifications or education of the applicants | BSc in Natural Resource Management<br>BSc in Applied Biology and Business Management<br>BSc in Chemistry<br>BSc in Biology<br>BSc in Agro-economic and Diploma in Agriculture |
| Length of work periods of the applicants | Combination of 2 years up to >17 years |
| Food categories or food industries of the applicants (categories noted in Table 6) | Strawberry farming – B<br>Brewery factories – D<br>Consulting activities – none<br>Catering factory – G<br>Meat factory – C<br>Flour and Bread factory – E |
| Training completed by the applicants | BRC course<br>Global GAP internal audit<br>Food safety inspection<br>HACCP training<br>ISO 22000 training at the QSAE |
| Gap identified during the evaluation of the applicants | Auditor training and auditing experience were lacking in these candidates which then did not qualify them for conducting audits for the ECAE.<br>No further action was taken other than the second advertisements in 2012. |

No further auditing personnel or technical expert evaluations were conducted by the certification personnel up to the date of the study 2 period. The review of the certification personnel during the study 2 period was then extended to the human resources department where an assessment of the internal pool of auditors and technical experts took place. The review focused on identifying personnel that may fall within the required food chain categories required to fulfil the scope of accreditation for the FSMS certification scheme as well as their compliance with the criteria set out in ISO/TS 22003 (2007). Annexures 3.3, 3.4, 3.5 and 3.6 were also considered during this review. The results of this assessment are included in Table 5.

Based on the evaluation of the internal personnel pool, the BSc in Agriculture (Food Science and Postharvest Technology), MSc in Chemical Engineering (Food Engineering), BSc in Agriculture (Animal Science) and BSc in Agriculture (Plant Science) qualifications were found to be the most appropriate qualifications for the FSMS certification personnel. BSc in Biology and BSc in Applied Chemistry included the basic entrance level qualification or education criteria and these people may be appropriate for certain certification activities provided they can provide evidence of their extension of knowledge in the food chain industry category to be audited. BSc Chemistry personnel will not be able to be used for FSMS certification activities.

It was therefore found that three persons from the internal personnel pool had the correct qualifications and could therefore be used for FSMS certification activities. On further review, however, the working experience of these three candidates did not support the particular requirements of ISO/TS 22003 in terms of working experience and can therefore not be used until such time that they provide evidence of compliance with the required working experience requirements.

After the review of the internal personnel pool, the information of the six external applicants was re-evaluated in order to establish if there is any possibility to make use of their services during any of the FSMS certification activities. The re-evaluation revealed that out of the six candidates, three had the relevant working experience in terms of the requirements of ISO/TS 22003 (2007), however, their qualifications were problematic and did not comply with the ISO/TS 22003 (2007) requirements.

**Table 5:** Summary of the qualifications found in relation to the food chain categories

| Qualification/ education | Compliance of subjects required by ISO/TS 22003 (2007) | Number of personnel found and working area | Link to particular food chain category (C, E and G required) |
|---|---|---|---|
| BSc in Agriculture (Food Science and Postharvest) | Yes | 2 –Testing laboratory | C, D, E, F, G, H |
| MSc in Chemical Engineering (Food Engineering) | Yes | 1 – Product Certification Team Leader | |
| BSc in Agriculture (Animal Science) | Yes | 1 – Product Certification | A |
| BSc in Agriculture (Plant Science) | Yes | 2 – Director Certification and Testing Laboratory | B |
| BSc in Plant Science | | 1 – Testing Laboratory | |
| BSc in Biology | No | 3 – Testing Laboratory (2) and ECAC Quality MR | None<br>May be able to qualify if additional subjects or courses are taken |
| BSc in Applied Chemistry | No | 7 – Certification and Testing Laboratory (6) | |
| BSc in Chemistry | No | 9 – Assistant General Manager, Team Leader Certification, Inspection and Testing Laboratory (6) | None<br>Not used at all, not even if additional subjects or courses are taken |

The three candidates had a combination of food safety training, which was limited to most probably internal audits and the related internal food facility training, therefore rendering them problematic towards audit training and audit experience. The issue of audit training and experience could, however, be resolved by assisting them in attending an auditing course and by giving them auditing experience.

Further to the re-evaluation of the six external applicants, the current QMS auditor for EA-code 03, Food products, beverages and tobacco, was also evaluated for his possible compliance with the ISO/TS 22003 (2007) requirements and therefore FSMS certification activities. He is an external person to the ECAE and has been conducting QMS and food safety audits for some time. His qualifications fell outside the ISO/TS 22003 (2007) requirements, however, he had many years' working experience in related food chain categories and sectors, he had attended various quality and food safety related training as well as auditing training and had some auditing experience in relation to food facilities. He has done consulting work on QMS and food safety systems for various food facilities which may support his working experience in the various sectors of the required food chain categories. This person was therefore also regarded as a possible candidate for supporting the FSMS certification activities.

In general, the review revealed some gaps in the processes applied to the evaluation of auditors. The processes applied to QMS auditor evaluations were applied to food safety auditor evaluations, which in a way could have been used as such, however, food safety auditors had to also be evaluated against the ISO/TS 22003 (2007) requirements and this highlighted the gaps in the process of identifying suitable certification personnel. The process for initial registration and ongoing maintenance of auditor competencies was regarded as problematic. The noted procedures were seen to be adequate in reflecting the basic requirements of ISO/IEC 17021, but the application of the procedures could not be found in auditor records. Gaps in the records of auditor competencies will impact negatively on the accreditation status and some work had to be done to ensure that records are complete and reflect all relevant requirements and application of the management system procedures.

### 4.3.4 Activity 4: Food facility

No preparation before the initiation of the study 2 period was conducted by the certification personnel to support objective (f) of the project, i.e. to 'conduct a factory assessment audit and proposal of corrective actions to be taken by the factory'. Relevant audit documents for the factory assessment had to be developed. This meant that during the study 2 period a suitable food facility had to be found that was willing to participate in the project. Finding a food facility that was ready for an ISO 22000 certification process was problematic taking in consideration the limited time allocated to specific activities of the study 2 period. A multinational beverage manufacturer who was willing to participate in the review was eventually found. This organization had a food safety audit two weeks before the site visit by the project participants. Its food safety management system was not based on the requirements of ISO 22000, but on the food safety requirements stipulated by the AIB International Consolidated Standard for Food Safety. The AIB International Consolidated Standard for Food Safety is regarded as a typical private specification applied by industry based most probably on customer requirements and/or the fact that the organization could not decide which food safety standards to apply and then just select one they felt comfortable with. Although the foundation of the majority of these private specifications is similar to ISO 22000, this particular one lacked the specific requirements of ISO 22000. This made it difficult for the project participants to assess the full extent of compliance of the organization's food safety management system with ISO 22000. Some relation to ISO 22000 could be identified as the management system reflected HACCP activities recommended by Codex, however, in the context of certification, all requirements of the certification standard must be demonstrated by the organization.

A typical stage 1 audit was conducted at the nominated food facility's site. All the certification processes relevant to a stage 1 audit were conducted by the certification personnel. The exercise was led by the project expert and supported by three nominated personnel from the ECAE. A site walkabout was conducted to assess the suitability of the working environment and infrastructure of the facility as well as a review of documentation relating to the food safety management system. This stage 1 audit practice was conducted in one day. The results of the stage 1 audit indicated that:

a. A total of 45% of the requirements of ISO 22000 had been noted as areas of concern implying that the particular requirements of the noted clauses had not yet been dealt with and/or included in the food safety management system. A total of 21 areas of concern were therefore raised during the audit.
b. A total of 43% of the requirements of ISO 22000 were found to be suitably dealt with in the documents presented during the audit.
c. A total of 12% of the requirements of ISO 22000 were not assessed during the audit and will need to be included in the stage 2 audit.

The concluding statement presented to the organization after the audit was that the food safety system presented during the audit did reflect the requirements of a HACCP based system as recommended by Codex. ISO 22000 (2005) does, however, require additional information to be established, documented and implemented in order to support a food safety management system and it was therefore evident that the organization will need to review and update the current food safety system to reflect the particular requirements of the ISO 22000 standard. This may also imply that the HACCP (Food Safety) team would need to revise their HACCP application methodologies as ISO 22000 (2005) is very specific in the application of the HACCP activities, studies and selection of control measures. In conclusion, the organization would need to apply the ISO 22000 standard to the food safety management system to ensure a positive outcome of a stage 2 audit. The maximum time of six months may be required to complete the review and update of the food safety management system, as well as the application of the management system analysis, verification and review processes required by ISO 22000 to provide evidence of the application of an effective food safety management system.

The stage 1 audit therefore revealed that a vast amount of information required by ISO 22000 (2005) had not yet been included in the establishment of the food safety management system of this food facility. The noted areas of concern would commonly need to be considered for inclusion into the system, therefore correction of all noted items, in order to support a positive outcome of a stage 2 audit. The audit further revealed that more time would need to be allocated in the future to conduct stage 1 audits, especially owing to the lack of audit expertise of the certification

personnel who participated in this exercise. The audit outcome also revealed that various areas of ISO 22000 had not been dealt with by the food facility in its food safety management system and thus implied that it would have been difficult for the same food facility to support the ECAE with the required stage 2 audit, which had to be conducted as an on-site witnessing assessment by the accreditation body, planned for mid-year.

As part of the objective to conduct a facility audit and to supply corrective action support, a recommendation was made to the food facility that a representative, typically the food safety team leader and/or Quality Manager attend a training course on ISO 22000. Parts of the food safety management system may then need to be reviewed and updated to support the inclusion of the ISO 22000 requirements.

The full certification process as reflected in Figure 8 could not be conducted, mostly owing to the status of the FSMS of the selected food facility. This stifled the capacity building project in that the completion of all relevant certification processes could not be realized, something that had to be completed to ensure a successful accreditation evaluation.

### 4.3.5 Activity 5: NQI institutions

The review revealed that no action had been taken on the study 1 action item list, which implied that the recommended mechanisms for the interaction and close cooperation between all parties of the NQI and the place of the CB within the NQI as reflected by Figure 2, had not been actioned. This result had a negative impact on the successes of achieving an accredited FSMS certification scheme within Ethiopia and was crucial now for the certification personnel to action the items noted in the action item list.

### 4.3.6 Activity 6: QMS and FSMS certification methodology workshop

No specific set-out training and/or workshop on the QMS and FSMS certification methodologies was conducted during the study 2 period. The decision not to conduct this workshop was based on the fact that no additional and/or specific FSMS certification personnel were selected and already participating in the FSMS certification activities. Secondary to this, the documentation relevant to the FSMS

certification aspects were not yet completed and were also not supported by a fully reviewed and corrected QMS. No new or completed information could be used for training.

Training and knowledge-sharing took place one-to-one with the certification personnel allocated to the product during the study 2 period. A larger audience of training included the participants of the stage 1 example audit where some of the required FSMS certification methodologies could be shared.

### 4.3.7 Activity 7: ToR comparison

The study 2 project period preparation included a pre-review of activities applied during the study 1 project, its outcomes and then the proposed work to be conducted as part of the study 2 period. One of the study 2 objectives to be achieved was the summarizing of the results and outcomes of the project in study 2 but also in relation to the overall capacity building project aimed at accredited FSMS certification in Ethiopia. A comparison was then conducted between the ToR of the study 1 and that of the study 2 projects in support of summarizing these activities and to conclude on action items between the study 1 and possible items remaining for the study 2 period outcomes in wrapping up the programme overall. This review revealed several similarities in the expected output by the two project periods. The result of the review is noted in Table 6 where similar colours indicate similar tasks and deliverables. An overall similarity between the two project periods was also indicated by this review and the results of the reviews are illustrated by Figure 22.

The similarities between the two capacity building projects may have been derived from the perspective of the need for additional intervention unknowingly not realizing that little to no progress was made in between the two interventions. The high percentage similarity of the two interventions may also be indicative of the lack of effective project and personnel control by the sponsor organization. The result of these similarities prevented the ECAE Certification Directorate to receive the value that had to be added by the interventions and placed an ongoing burden on them to complete the project without possible further support.

**Table 6:** Summary of the comparison findings made on the ToRs between the study 1 and study 2 capacity building projects

| Study 1 | Study 2 |
|---|---|
| **Main tasks** | |
| Establish **documentation** including manual and relevant work procedures for the food safety management system accreditation of the ECAE and identify gaps as well as recommended measures to be taken in accordance with ISO/TS 22003 and/or HACCP. | **Advise and support** the Certification Directorate of the ECAE in the process of **developing, implementing and maintaining** food safety management certification system benchmarking international best practice. |
| Assess **personnel** qualifications, develop **competence matrix** of the system certification team (for FSMS lead auditors, auditors, technical experts, certifiers, those conducting contract review, and internal auditors) and recommend training or twinning arrangements based on the identified gaps. | **Introduce international best practices** with respect to internationally harmonized conformity assessment procedures. |
| Provide a **two-day** orientation **training** on the established and implemented FSMS certification process and documentation (both for the internal purpose of the ECAE and for certification of firms). | **Devise a mechanism** for ensuring close cooperation with various **regulators** and other **NQI institutions**. |
| Conduct **factory assessment**, consultancy audit and propose corrective actions to be taken. | **Support** the establishment of effective certification **policy and strategy**. |
| **Check and support** home office **documentation**, which are planned for five days out of the 25 total days. Examine the existing documentation system and identify nonconformities in the view of envisaged accreditation (in line with the requirements | **Review** the adequacy of the established **FSMS-**related **draft documents** and assist in establishing the missing ones. |
| | Conduct **factory assessment audit** and propose corrective actions to be taken. |
| | **Assist** in establishing **certification** |

| Study 1 | Study 2 |
|---|---|
| of ISO/TS 22003, and ISO/IEC 17021) and propose corrective actions. | **personnel competence** development scheme. |
| | **Establish** appropriate **selection criteria** for **certification personnel** with respect to educational qualification, industrial and work experience as well as audit experience relevant to the accreditation scopes only in the categories of C, E and G. |
| | **Develop** and **deliver** progress reports, proposals, requirements documentation and presentations periodically. |
| **Deliverables** | |
| The expert shall deliver all the required **documentation** in line with the requirements of ISO/TS 22003, ISO 22000 and the accreditation body including the quality manual to the ECAE and ECPB (in soft and hard copy). | The expert shall deliver all the required **documentation** in line with the requirements of ISO/TS 22003, ISO 22000, ISO/IEC 17021 and the accreditation body, including the quality manual to the ECAE, Certification Directorate (in soft and hard copy) and a summary report of accomplished activities to the NQI Project Office. |
| The expert shall deliver a gap analysis **report**, relevant **documents** and checklists, criteria documents, specific conditions and requirements, and an FSMS development, implementation and accreditation action **plan** (in soft and hard copy). | The expert shall deliver a **factory assessment consultancy** audit report, relevant documents and checklists, criteria documents, specific conditions and requirements, and an FSMS development, implementation and accreditation action **plan** (in soft and hard copy). |
| The expert shall organize a **two-day seminar or workshop** on the overall FSMS certification system. | The expert shall organize a **seminar or workshop** on the documentation and the overall FSMS certification system. |

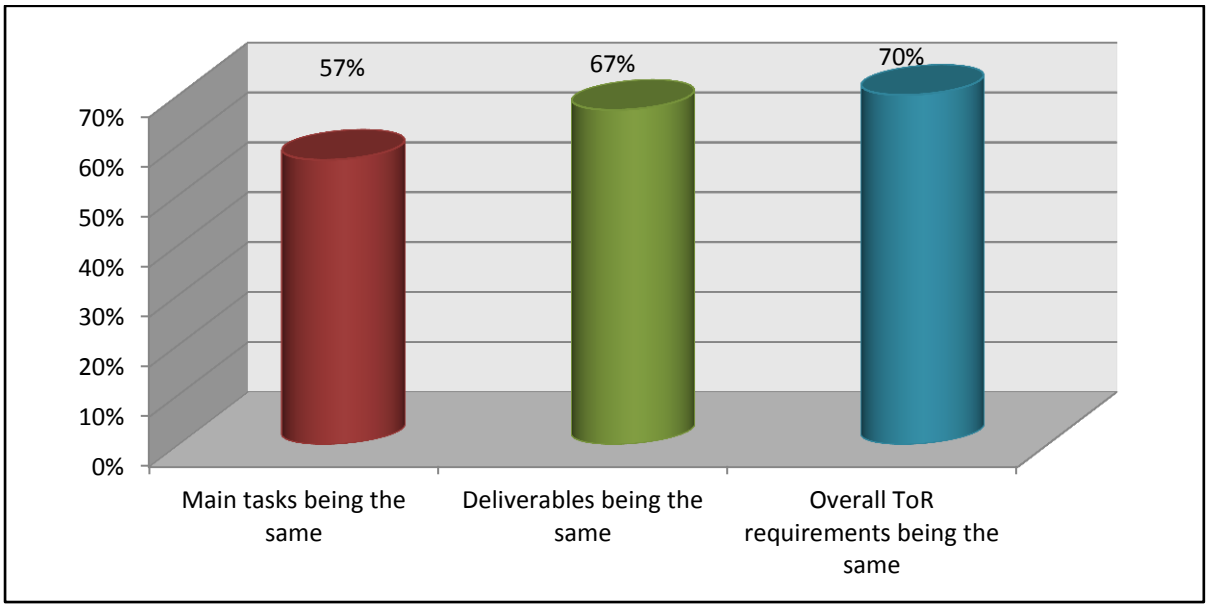


**Figure 22:** Graphic illustration of the percentage comparison between the ToRs of study 1 and study 2 of the capacity building project

### 4.4 Project study outcome recommendations made

Based on the results of the comparative progress study no new recommendations could be made that would have supported the completion of the development and implementation of the FSMS certification scheme leading to its accreditation. The study 2 period had to revert to the study 1 action item list and through repetitive work reiterate the actioning of the action item list. A minor number of additional items were added to this action item list. This in a way created an overburdened outcome for the certification personnel and project participants.

The action item list then compiled as an outcome of the study 2 period is reflected in Table 7. The study 1 outcomes remained in the action items list and are noted in brackets as ‘Study1 – and its related number’. This list then also includes the newly added actions identified during the study 2 period.

A total of 80,4% of the study 1 action items were carried over to the study 2 action list and an additional 30 new items were added. The study 2 action item list therefore concluded with 126 action items to be completed to secure a successful accreditation status of the FSMS certification scheme once the QMS development and implementation were completed. Figure 23 gives a graphic illustration of the final action item category comparison in terms of distribution of action items to be addressed.

### 4.5 Discussion

The study 1 period concluded with an action item list with 114 points which was laid out into a logical sequence of activities to be carried out over approximately eight months. This action item list methodology for project management has been shown by literature as an effective means to conduct and ensure effective planning of projects, no matter the format, and that it had a higher likelihood of achieving the desired results (Scott Sutterfield, Friday-Stroud and Shivers-Blackwell, 2006). Nearly two years passed after the submission of this action item list, which in some cases could be a common time frame for the implementation of complex projects such as the implementation of a certification scheme, noted in literature on studies conducted on project management, i.e. as noted by Scott Sutterfield, Friday-Stroud and Shivers-Blackwell in 2006. The assessment of progress made with the study 1

**Table 7:** Study 1 action items carried over (noted in brackets) as well as the study 2 capacity building project additional action items identified

| No | Action items |
|---|---|
| **A** | **Food safety management system certification scheme in general** |
| 1 | (Study1-1) Identify a specific nominated person (project champion) to take the project forward up to accreditation |
| 2 | Appoint a food manufacturing related person to manage the FSMS scheme including all aspects of the scheme in relation to this proposed action item list |
| 3 | (Study1-2) Nominate relevant participants of the project and determine biweekly project follow-up actions or meetings to pace the completion of the project |
| 4 | (Study1-3) Identify a more detailed action item list, time frame and detailed responsibilities for the completion of the project |
| **B** | **Certification personnel** |
| **B1** | **Application review committee members – Quality Manager – Certification** |
| 1 | (Study1-1) Identify an adequate pool of reviewers that comply with the education, food safety training and audit training criteria of ISO/TS 22003 |
| 2 | (Study1-2) For those that do not have food safety training, schedule, ensure that they attend and verify such training |
| 3 | (Study1-3) For those that do not have audit training, schedule, ensure that they attend and verify such training |
| 4 | (Study1-4) For the pool identified, schedule the assessment of its competencies as stipulated by 7.2.2.4 of ISO/TS 22003 (2007) |
| 5 | (Study1-5) Establish corrective actions for those individuals who do not comply with the competency evaluation |
| **B2** | **Certification decision committee – Team Leader – Certification** |
| 6 | (Study1-6) Identify an adequate internal pool of certification committee members who comply with the education, food safety training, audit training and work experience criteria of ISO/TS 22003 – within the food chain categories selected |

| No | Action items |
|---|---|
| 7 | (Study1-7) Identify an adequate external pool of certification committee members who comply with the education, food safety training, audit training and work experience criteria of ISO/TS 22003 – within the food chain categories selected |
| 8 | (Study1-8) For those that do not have food safety training, schedule, ensure that they attend and verify such training |
| 9 | (Study1-9) For those that do not have audit training, schedule, ensure that they attend and verify such training |
| 10 | (Study1-10) For the pool identified, schedule the assessment of its competencies as stipulated by 7.2.3.2 of ISO/TS 22003 (2007) |
| 11 | (Study1-11) Establish corrective actions for those individuals who do not comply with the competency evaluation |
| **B3** | **Impartiality committee – Director – Certification** |
| 12 | The committee needs to meet in 2013 and evidence provided that food safety has been included in the agenda and discussions took place |
| **B4** | **Auditors – Team Leader – Certification** |
| 13 | (Study1-17) From the list of the internal pool and the external applicants, list all candidates that can be considered able to qualify as auditors and technical experts |
| 14 | Prepare a 'draft' list of possible food safety certification personnel candidates and present it to the Accreditation Body for preliminary evaluation during the 2013 accreditation visit (recommended candidates as reflected by the study 2 report) |
| 15 | Send out the letter drafted in May 2013 to the training institutions in order to gain knowledge of the types and contents of education or qualifications required for food safety certification personnel |
| 16 | (Study1-18) Draw up a list of acceptable qualifications as well as acceptable institutions that do and will comply with the requirements of ISO/TS 22003 – use these criteria as internal criteria for the acceptable education requirements |

| No | Action items |
|---|---|
| 17 | (Study1-19) From the final list of possible acceptable candidates, for those candidates who do not have food safety training, schedule, ensure that they attend and verify such training |
| 18 | (Study1-20) From the final list of possible acceptable candidates, for those candidates who do not have audit training, schedule, ensure that they attend and verify such training |
| 19 | (Study1-21) From the final list of possible acceptable candidates, for those candidates who do not have audit experience, plan how the audit experience can be gained |
| 20 | (Study1-22) For those that do not have the immediate correct work experience, set up equivalent work experience such as retailing, inspection or enforcement. Determine how to meet the required work experience for those that are lacking |
| 21 | (Study1-23) For the final pool identified, schedule the assessment of its competencies as stipulated by 7.2.2.4 of ISO/TS 22003 (2007) |
| 22 | (Study1-24) Evaluate the list of registered auditors on the IRCA list to determine auditors and experts in Ethiopia and/or countries surrounding Ethiopia |
| 23 | Evaluate the list of food safety auditors of SGS to determine the location and details of food safety auditors within the selected food chain categories |
| 24 | From the list of SGS auditors, initiate communication with them and request their competency details in preparation of their use within ECAE Cert. Prepare the required auditor agreement actions, such as declarations for the purpose of impartiality and confidentiality |
| 25 | (Study1-25) Communicate with the auditors on the IRCA list to determine their interest in auditing for the ECAE |
| 26 | (Study1-26) Identify a pool of experts (internal and/or external) in the selected food categories as these experts may be used for the purpose of auditing and certification decisions per certification client. Estimate two nominations per category |
| 27 | (Study1-27) Communicate to the accreditation body the proposed auditor criteria |

| No | Action items |
|---|---|
| | and action plan to achieve compliance with ISO/TS 22003 |
| 28 | (Study1-31) Set up auditor or expert agreements for the selected external auditors or experts |
| 29 | (Study1-33) Determine the time frame and methodologies for establishing 'calibration' sessions for auditors and experts |
| 30 | (Study1-34) Determine the contents of calibration sessions and/or the means to identify calibration session contents |
| 31 | (Study1-35) Develop a list of technical experts relating to the selected food chain categories |
| 32 | (Study1-36) Nominated audit teams per food chain category which would need to indicate overall compliance with the 'selection of audit teams' requirements of 7.2.6 of ISO/TS 22003 (2007). Predetermination of such teams are recommended |
| 33 | Assess all auditor files and make sure that all relevant records are a 100% complete and that records, i.e. C.V.s or training records, have been updated. The newly drafted auditors log should be used. Continual professional development records are to be added to auditor records |
| 34 | Make a decision on the support of training and audit experience of applicant auditors and/or technical experts |
| 35 | Determine the contractual arrangements when training and/or audit experience is provided |
| 36 | Draw up a proposed list of possible FSMS certification personnel candidates (the four external personnel identified during the visit) and present it to the Accreditation Body for comments. The proposal should also include the means of having the candidates 'qualified' in terms of audit experience, audit and food safety training. They are to be used the get the FSMD scheme off the ground, although their qualifications might not be correct, credit may be given to their working experience, food safety training and auditing experience |
| 37 | Ensure that a food manufacturing or food handling knowledgeable person is used to evaluate FSMS certification personnel against the set criteria |

| No | Action items |
|---|---|
| 38 | Arrange for an overall FSMS certification personnel training session on the FSMS documents derived from the two interventions as well as some technical introduction training on ISO 22000 once the system has been launched |
| **C** | **Certification scheme process and documentation** |
| **C1** | **Certification schemes – Director – Planning and marketing** |
| 1 | (Study1-1) Determine the need for a food safety certification scheme |
| 2 | Gain knowledge of food safety certification schemes available in Ethiopia and/or provided by other CBs |
| 3 | Study the contents of other food safety certification schemes in order to determine the possible gaps between such a scheme and the ECAE Cert FSMS certification scheme |
| **C2** | **Brochure – Director – Planning and marketing** |
| 4 | (Study1-2) Review the contents of the brochure to meet the ECAE information |
| 5 | (Study1-3) Review the explained certification process in comparison with the new process included in the quality manual and the certification agreement during the site visit |
| 6 | Update the divisional brochure to match the work done on documentation during the 2013 intervention |
| 7 | Ensure that the company and divisional brochures are aligned with the same information |
| **C3** | **Certification certificate – Director – Planning and marketing** |
| 8 | (Study1-4) Investigate a suitable means of ensuring authenticity of the certificate |
| **C4** | **Quality manual – Quality Manager – Certification** |
| 9 | Changes made to the manual need to be communicated to the relevant certification personnel |
| **C5** | **Documentation in general – Quality Manager – Certification** |
| 10 | (Study1-6) Establish a planning session for the overall structure development for documentation of the Certification Directorate to identify the generic |

| No | Action items |
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| | documents, scheme specific technical documents, levels of documents within the directorate and departments and then the possible unique identification in terms of prefixes and numbering<br>(Refer to the recommended master list of documents given as the recommendation for the management system structure) |
| 11 | Ensure interaction with the organizational management system structure. Ensure communication with the MR and request his support with the completion of the recommended system certification documentation structure |
| 12 | (Study1-8) Ensure that all reviewed and updated documents reflect the document history as 'Reviewed and updated to reflect incorporation of the FSMS certification scheme' with authors and the effective date 'Sept 2011'. |
| 13 | (Study1-9) Review all documents to ensure that the writing style is 'eurostile' and in font size '12'. Add this information to the control of documents procedure as part of the writing requirements of a document |
| 14 | (Study1-10) Review all documents to ensure a standard use of the template for the contents of documents |
| 15 | (Study1-11) Decide on the identification of documents in terms of the prefixes to add or not to add a 'Q' for QMS-specific documentation and an 'FS' for FSMS-specific documents |
| 16 | (Study1-12) Review all documents and replace ISO/IEC 17021:2006 with the 2011 version. |
| 17 | (Study1-13) Review all documents and add ISO/TS 22003 as a reference document |
| 18 | (Study1-14) Review all documents and add the IAF mandatory references to where they are appropriate in the specific document |
| 19 | (Study1-15) Review all documents to ensure accurate reference is made to 'referenced documents' for each document and not to include ISO 9001 or ISO 22000 if it does not influence the use to the specific procedure |
| 20 | (Study1-16) Review all documents to ensure the use of the new reference to the certification documentation as 'management system certification' |

| No | Action items |
|---|---|
| | documentation |
| 21 | (Study1-17) Decide on the purpose, use and actual contents of paragraph 5, Indicators of all procedures, then either remove it from all procedures or allocate the indicators in all procedures |
| 22 | (Study1-18) Review all documents to ensure that the listed abbreviations under point 6 of the procedures are used in the body of the document and/or where abbreviations are used in the body of the document, that they are listed and explained under point 6. |
| 23 | (Study1-19) The approval block appearing in documents seems to move around depending on the user and/or during printing. The typing format of this block needs to change from a 'picture block' to a 'table block' as this will assist in keeping the approval block in one place during the use and printing of documents. All documents are to be review and corrected to ensure the approvals block remains in the same place |
| 24 | (Study1-20) Review all procedures to remove bullet points in the process description paragraphs and replace them with 'enters' so that each new sentence starts at the left-hand side of the column |
| 25 | (Study1-21) Review the stand-alone vision, mission, quality policy, impartiality policy and confidentiality policy as those contained in the quality manual were minimally corrected in terms of the English |
| 26 | (Study1-22) Review documents against the comments and recommendations made in the document review list as some were dealt with and some may still need to be discussed and decided on |
| 27 | Allocate responsibilities and authorities to the Quality Manager in order for him to conduct his 'management representative' work in relation to the requirements of ISO/IEC 17021 |
| 28 | Plan a training session on the FSMS certificating scheme documents and processes when actual certification personnel become available |
| 29 | Deal with the comments on documentation noted in the report |
| 30 | Complete the document review of the remaining documents not assessed by |

| No | Action items |
|---|---|
| | the expert during the study 2 period visit. See the notes in the report. Correct the documents if required or note if a particular food safety document is required |
| **C6** | **Electronic versions of documents – Quality Manager – Certification** |
| 31 | (Study1-23) Identify the QM to be the 'master' holder of electronic versions of all documents |
| 32 | (Study1-24) Determine the documentation filing set-up to clearly identify general management systems, quality specific and food safety specific documents |
| **C7** | **Management review – Quality Manager – Certification** |
| 33 | (Study1-25) Ensure that the next management review includes aspects of food safety certification activities |
| **C8** | **Internal audits – Quality Manager – Certification** |
| 34 | (Study1-26) Establish an audit programme reflecting areas and processes of importance |
| 35 | (Study1-27) Update the internal audit checklist to reflect the requirements of ISO/IEC 17021 (2011) as well as the specific requirements of ISO/TS 22003 |
| 36 | (Study1-28) Establish and document internal auditor selection criteria |
| 37 | (Study1-30) Update the process flow diagram for the internal audits |
| 38 | (Study1-31) Ensure the availability of an internal auditor with a background in the food safety specific requirements, not only of ISO/TS 22003, but also the technicalities of the audit documentation for ISO 22000 |
| **C9** | **Corrective and preventive action – Quality Manager – Certification** |
| 39 | (Study1-32) Split the corrective action process from the preventive action process |
| 40 | (Study1-35) Define corrective action and preventive action |
| **C10** | **Customer surveys – Quality Manager – Certification** |
| 41 | (Study1-36) Establish for example an 'excel' spreadsheet containing a list of the customers with their identify numbers (i.e. the application number) and then the 'year' numbers in order to establish a selection matrix to indicate which |

| No | Action items |
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| | customers over a period of years have been selected to participate in the surveys. The list will permanently be extended as customers are added. Colours may be used to indicate if customer have been suspended or extended or have a decreased scope, etc. as their certification status may influence the selection of participating in the survey process |
| 42 | (Study1-37) Correct the number for the survey form to be a '1' instead of a '2'. |
| **C11** | **Auditing processes – Quality Manager – Certification** |
| 43 | Decide on a selected or nominated PRP standard to support the PRP aspects of the ISO 22000 standard during training, implementation and then certification |
| 44 | Draw up an audit checklist for PRPs that reflects the selected standard(s) and related legal requirements<br>Checklist(s) can also be food chain sector specific and/or generic |
| **D** | **Activities and interested parties related to certification** |
| 1 | The nominated FSMS certification scheme coordinator are to set up a regular, i.e. once a month, meeting to discuss progress made with the action items noted in this action plan as well as to report on progress made with the development of the FSMS certification scheme activities |
| **D1** | **Standards and library – Head – Documentation and publications** |
| 2 | (Study1-2) Make the required or selected standards available |
| 3 | Decide on the most appropriate standard or set of standards for PRPs to support ISO 22000 implementation as well as certification |
| **D2** | **Training and consultation programmes for FSMS – Training and technical support directorate** |
| 4 | (Study1-3) Update the training materials to reflect ISO 22000 specific HACCP plan requirements versus only using Codex examples |
| 5 | (Study1-4) Plan to re-attend a five-day training session to establish 'correctness' of information trained so that it is not in conflict with certification expectations |
| 6 | (Study1-5) Plan to have the training provider observe one or two FSMS |

| No | Action items |
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| | certification audits to verify contents of the training material against the certification processes |
| 7 | (Study1-6) Plan for the participation of the consulting personnel to participate in training and auditing activities to ensure correct implementation recommendations to the certification client |
| **D3** | **Ethiopian food handling market, marketing and new business development – Director – Planning and marketing** |
| 8 | (Study1-7) Investigate the need and readiness for ISO 22000 certification |
| 9 | (Study1-8) Investigate the food sectors currently available in Ethiopia |
| 10 | (Study1-9) Investigate the preferred food safety certification scheme |
| 11 | (Study1-10) Determine number and types of food businesses – multinationals or local or SMMEs, etc. |
| 12 | (Study1-11) Establish current certified status and willingness to move over |
| 13 | (Study1-12) Establish marketing strategy to move already certified clients to the ECAE |
| 14 | (Study1-13) Establish the importance of accredited certification and/or no need to have accredited certification |
| 15 | (Study1-14) Develop marketing material and the marketing means for the FSMS certification scheme – add the relevant supporting services |
| 16 | (Study1-15) Develop a certification certificate for the FSMS certification scheme, and authenticate the certificate |
| **D4** | **Laboratory services – Director – Laboratories** |
| 17 | (Study1-16) Determine the feasibility of microbiological and food chemical testing |
| 18 | (Study1-17) Establish programmes to support the outcome of the survey |
| 19 | (Study1-18) Establish marketing material for the establishment of services to the food handling industry |
| 20 | (Study1-19) Revise the scope of accreditation to include the most requested tests of the food handling industry |

| No | Action items |
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| **D5** | **Human resources – Human Resources** |
| 21 | Reassess the level of authority for the correct placement of staff, and to have in place a professional and personal development plan and/or strategy for employees |
| 22 | Set up a means or process for departments to communicate with HR their personnel requirements criteria in order for HR to conduct effective recruitment and employment of personnel |
| 23 | Personnel CVs are to be updated to reflect more technical information, i.e. what areas specialized in during testing or inspection or auditing. Technical information is to assist with linking personnel to NACE codes and/or food chain categories and their sectors |
| **D6** | **Financial and liability risk assessment – Finance and supplies Director** |
| 24 | (Study1-22) Determine the feasibility to be held accountable for the failure of a certified FSMS |
| 25 | (Study1-23) Conduct a risk assessment for liability based on food safety |
| 26 | (Study1-24) Conduct a financial risk assessment for the finances and sources of income of the FSMS certification scheme |
| 27 | Include in the financial risk assessment the financial impact of other possible FSMS certification schemes, i.e. FSSC 22000, as some of them carry a licence fee payable to the scheme owners |
| 28 | (Study1-25) Establish a means to annually review the adequacy of the liability cover for the certification activities |
| **D7** | **Legal services – Legal services** |
| 29 | (Study1-26) Review the certification agreement to ensure it is within Ethiopian written legal requirements |
| 30 | (Study1-27) Review the auditor or expert agreement to ensure it contains all the required information and is written within the Ethiopian legal requirements |
| **D8** | **Ethiopian food legislation – Director General** |
| 31 | (Study1-28) Through the Director General initiate communication with the |

| No | Action items |
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| | relevant role players for setting food legislation |
| 32 | (Study1-29) Nominate a certification person to be a contact person or participant with the role players to support the establishment of food legislation. This may also include the setting up of compulsory standards |
| 33 | (Study1-30) Get copies of the relevant laws or draft laws |
| 34 | (Study1-31) Evaluate their contents against the required PRP requirements of the ISO and GMP standard and determine the feasibility for use and for auditing and implementation by the organization |
| 35 | (Study1-32) Decide on the 'interim' decision on recommending food legislation to a certification applicant as well as the conducting of certification with a food handler with the interim plan |
| 36 | (Study1-33) Establish a process to have in place processes for when the food legislation is passed and becomes a legal requirement, how to communicate to certified clients, the period involved in allowing certified clients to incorporate the legislation and the certification process thereof and/or suspension of certification when non-compliance with legislation is identified after the communicated date of implementation |
| 37 | (Study1-34) Interpret and understand the requirements and needs for food stipulated by the Federal Negarit Gazeta of 13 January 2010 – Proclamation no 661/2009, and also its support of other related food regulations and implications |
| 38 | (Study1-35) Draw up the necessary criteria documents and/or checklists to support the certification process |
| 39 | (Study1-36) Set up a training programme on the established legislation |
| 40 | (Study1-37) Ensure that the certification personnel attend the food legislation training programme |

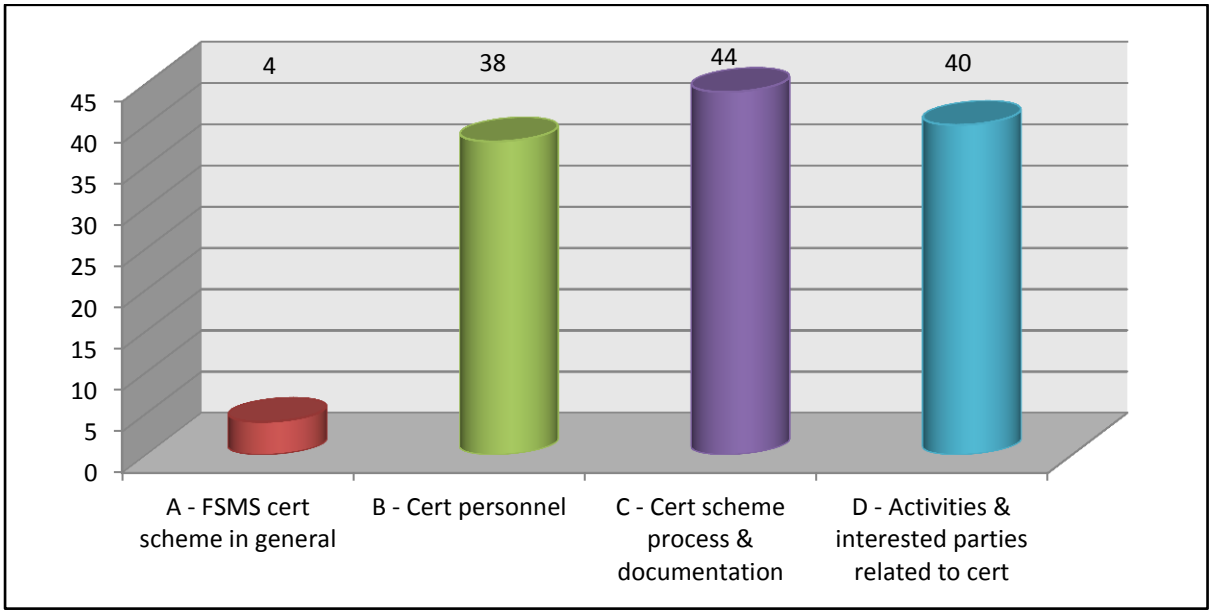


**Figure 23:** Graphic illustration of the final action item category comparison

action item list led to the study period 2 to absorb this 114 points and had to because of its lack of completion and because of the extension of the capacity building activities of study period 2 which then concluded with a 126 point action item list. This capacity building project was motionless based on the fact that nobody took responsibility for the management of the noted timelines and action items created as outcomes from the study 1 period and may even have been influenced by the lack of understanding of the complexity of the project and the level of management that was required to see it through. Similar problems with projects of this nature have previously been reported by Scott Sutterfield, Friday-Stroud and Shivers-Blackwell (2006).

The study 2 period theoretically ended on the first day of its intervention. The lack of progress made with the study 1 period action item list stopped all innovations planned to move the capacity building project forward towards its finalization with the focus being the achievement of an accredited status for the FSMS certification scheme for Ethiopia. A certification scheme desperately needed in support of the economic growth for Ethiopia as equal participation in ensuring food safety through the multiparty participation of industry, government and the market (Qin, 2010).

Since all project arrangements had been made and the expert already being on-site for the contracted study period time and without the option of stepping back from the project and allowing the needed completion of the action item list, new innovations for this study period had to be created to meet the set out requirements of the ToR. The comparative progress assessment had to be conducted in a way where not only the progress was to be measured, but also actioned to forcefully reflect progress made with the project.

The action item list of the study 1 period still had to be used for the progress assessment as it formed part of the foundation of the progress study remaining the reporting tool back to the management of the organization and the sponsor organization. The list was further used to identify which activities can be dealt with during the study period in support of moving the project forward towards completion.

A similar but more detailed review of the QMS documentation of the Certification Directorate and its certification personnel was conducted. The documentation review revealed a similar status of the QMS set of documents and FSMS certification processes as what was found during the study 1 period. A second recommendation was put forward to simplify the design of the QMS in terms of the documentation set-up, filing and availability. The set-up moved from a three-level structure to a proposed ten-level structure system. Time constraints did not allow for the completion of the transformation from the three- to ten-level structure and certification personnel was tasked to complete this process. A more detailed review of the FSMS certification personnel reiterated the gap that had to be dealt with to meet the requirements for international best practices of personnel carrying out FSMS certification. Compliance with the provisions of ISO/TS 22003 (2007) remained the biggest challenge. The identification of the FSMS certification personnel competency gap was further supported by the outcomes of the facility visit where the audit participants reflected their struggles in conducting FSMS certification audit work with the focus being on ISO 22000. It remained vital to the success of the certification scheme that the auditors are competent and are perceived to be competent by the audit client in conducting the certification activities as this has been shown in literature to have a positive impact on the meaningfulness of audits and therefore certification towards food safety controls (Läikkö-Roto and Nevas, 2014).

A facility visit was again part of this study period, however, the facility selected did not apply ISO 22000 for the development of their FSMS. The practical exercise that had to be applied in support of competency capacity building could not fully be realized based on the fact that the FSMS assessed was not based on ISO 22000 and therefore the learning of auditing against ISO 22000 could not take place.

The certification of an FSMS by the Certification Directorate was further complicated by the fact that no significant improvement towards possible certification support functions, services or relevant stakeholders and role players could be shown. Various certification processes and in some cases food safety specific certification rules or procedures could not be finalized due to the lack of these aspects of the certification operations, aspects such as legislation, testing laboratories, standards, knowledge of market needs, and training or consulting programmes.

In the light of assessing the progress made with the project and its failure to move forward, a comparison of the ToRs of the two study periods was triggered because of the objectives and the result of the two study periods being similar. Questions before the study 2 period was raised by the expert in terms of the reason behind the repetitiveness of actions between the 2 study periods. It was reasonable to believe and is argued in literature presented on project management that the successful achievement of a project is based on the clear articulation of the project needs, stakeholders and outcomes based on the vision of the required achievement (Scott Sutterfield, Friday-Stroud and Shivers-Blackwell, 2006). Communication towards and explanatory information received on this posed question by the expert were limited and it was not expected or accepted that the expert can be of a position to raise such a question. The restrictive responses to the new ToR and its contents should have highlighted the possibility of communication barriers between the beneficiary and sponsor organization, and then certainly back to the expert. These communication barriers could have been derived from the long-term intervention and interaction by various stakeholders of the project and/or could have been created by simple misunderstandings or even the basic barriers of communication such as cultural differences, different views of the world or life temperaments, types of thinking, age, education, and professional and language differences (Klimova and Semradova, 2012). The second study period had to unfold based on the ToR which was developed by the Certification Directorate in terms of its specific needs and the way it saw the project unfolding. These decisions were carried out in communication with the sponsor organization as it is common for the process of ToRs to unfold like this. Approval of projects and issue of contracts are based on ToRs of the various phases of projects and allocation of experts complying with the relevant set-out ToR. Approval of ToRs is carried out by both the beneficiary and sponsoring organization. This process failed the expert in terms of support and backup for seeing the project through to its completion.

## 4.6 Conclusion

The FSMS certification scheme of the ECAE had not evolved into a completed certification scheme during the two capacity building projects periods over two years.

Evidence of the effectiveness of the capacity building project towards the successful accreditation as well as sustainability for FSMS certification in Ethiopia could not be reported on after completion of the study 2 period. A possible third phase of intervention had to be created to ensure the completion of the project, something that was highly unlikely based on the funding rules and requirements of this project which was similar to the rules of so many other sponsored capacity building projects.

The similarities of the ToRs of the two study periods had a major role to play in the success of application of interventions from the expert. The study 1 results and effective application of the action item list should have formed the foundation on which the study 2 period and activities had to be based. But due to the lack of application of the action item list from study period 1, the need for the intervention by an expert to build the required capacity for FSMS certification remained the same as for study period 2. The need was not incorrect, the management of the project work failed the beneficiary.

A further negative impact on the results of the project may have been based on the lack of identification of a certification project ‘champion’, ineffective communication about the project work, ineffective project management and people and operational change management which was never considered and therefore not put into the overall capacity building programme for ECAE.

## 4.7 References

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ISO 14001. (2004) *Environmental management systems – Requirements with guidance for use*, Geneva: ISO.

ISO 19011. (2011) *Guidelines for auditing management systems*, Geneva: ISO.

ISO 22000. (2005) *Food safety management systems – Requirements for any organization in the food chain*, Geneva: ISO.

ISO/IEC 17021. (2011) *Conformity assessment – Requirements for bodies providing audit and certification of management systems*, Geneva: ISO.

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Klimova, B.F. and Semradova, I. (2012) 'Barriers to communication', *Procedia – Social and Behavioural Sciences*, vol. 31, pp. 207–2011. https://doi.org/10.1016/j.sbspro.2011.12.043

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# CHAPTER 5

# CONCLUSION AND RECOMMENDATIONS

## 5.1 Summary of main findings

An overview of the main findings per chapter of the study is listed below:

### 5.1.1 Chapter 1

- Differences between quality and food safety and their impact on the health of the consumer versus the perception and expectations of food by the consumer were noted.
- Food safety risks, although seemingly controlled through the application of various management systems, continues to lead to the outbreak of food-borne disease in both developed and developing countries.
- Trading in food became a market access commodity and is used for sustainable development from small scale food handlers to multi-national organizations from the concepts of a general livelihood activity to a formal business.
- Ever changing needs, revealed, as well as requirements and standards for the management of food production in terms of its quality and food safety characteristics seeing it as either assisting or restricting trade.
- The conflict in Africa between the concepts of food security versus the need for food safety and the obligation to meet dietary and health needs.
- Recognizing the on-going constraints of Ethiopia to comply with the WTO requirements set for member countries in terms of trade in aid of economic development and alleviation of poverty.

### 5.1.2 Chapter 2

- It was reiterated that WTO members are obligated to develop and apply a NQI framework in support of continued economic development.
- Honouring TBT and SPS agreements of the WTO through application of conformity assessment, for example applying accredited FSMS certification in aid of food trade based on International Standards and best practices should be encouraged.
- Adhering to the principle of fair trade set by the WTO in promoting economic development.
- Taking cognisance of the challenges faced by developing countries in the development and application of a NQI.

- Recognising a continued need by developing countries for financial support in developing and applying a NQI through the promotion of sponsor based capacity building projects.
- Noting the need for effective assessment and identification of needs of developing countries when sponsor based capacity building projects are initiated.

### 5.1.3 Chapter 3

- Most aspects of a NQI framework were established while others were still in the process of being developed. Aspects required for the certification of food safety to be effective and in-line with the requirements and purpose of the ISO 22000 (2005) standard also remained to be established.
- The Certification Directorate of the ECAE was already accredited for management system certification, however, their QMS revealed inadequacies in supporting the extension of their certification work to include food safety.
- There was a noticeable lack of knowledge among food safety personnel on the availability and application of legislation and standards in support of food safety certification.
- Difficulty in attaining and/or purchasing ISO-related food safety standards by the public and therefore the food handler.
- Overall lack of knowledge of the market need for food safety certification and the FSMS certification scheme of choice or need required for the exporting of food products, other than purely ISO 22000.
- Lack of knowledge on the readiness of the Ethiopian food handling market to be certified to an ISO standard.
- In spite of the possibility of the presence of food facilities ready for food safety certification, inadequate effort was applied to give the proposed auditor pool opportunities for auditing in these facilities to build knowledge and capacity in support of the ISO/TS 22003 (2007) auditor competence requirements.
- A lack of updating FSMS course material to reflect the needs of Ethiopia as well as relevance of legislation and standards specific to the country and its incorporation and relevance to certification.
- Difficulty for the industry to have food verified for the presence of food safety hazards.

- Lack of nomination of a specific project champion for the FSMS certification scheme development period as well as inadequate responsibilities and authorities allocated to the quality manager of the Directorate who could have led the project.
- Competency inadequacies of the proposed auditor pool and other certification personnel to demonstrate compliance with the criteria set in ISO/TS 22003 (2007) with regards to food safety auditing and decision making.
- Not heeding expert advice in relation to the development of the documentation and methodologies required to audit FSMS and to manage the FSMS certification scheme.

### 5.1.4 Chapter 4

- No progress in addressing the action items from the first study period going into the second study period.
- Negligible progress with the QMS status of the Certification Directorate after two years with subsequent revision and modification to accommodate the requirements of the project.
- Reiterating the competency gap of the proposed auditor pool and certification personnel and the fact that no further progress has been made to narrow the gap since the first sturdy period.
- Most of the facilities selected for capacity building and auditor competency training did not have an ISO 22000 or similar FSMS in place, resulting in the ineffective use of time.
- Stifling results of the project that may have arisen from the duplication of activities and objectives in the ToRs between the two study periods whereto the expert had to work towards.
- Ineffective project management, project communication and coordination between the beneficiary and the sponsor.
- Impact of the difficulty to change amongst project personnel and culture dynamics between the project personnel further hindering the achievement of the objectives and goals of the project as a whole.

## 5.2 Conclusion

The overall focus of the project was to build capacity towards the Ethiopian conformity assessment aspect of a NQI to improve the competitiveness of the industry in line with best international practices through the means of applying accredited certification of FSMSs against the recognized international standard, ISO 22000. The impact of the role of central governmental bodies in the need and acceptance of conformity assessment as a recognized technical competence for bilateral and multilateral free trade agreements originated from the 'WTO – TBT Agreement, Article 6. An accredited FSMS certification scheme for Ethiopia was inevitable and so crucial to ensure economic development through cross-border trade of food.

This capacity building project was based on sponsorship through a donor organization in aid of on-going economic growth and poverty reduction of a developing country, one of many projects and examples initiated by governments in support of global goals for economic growth set out, for example in the report published by the UK Department of International Development (DFID) where trading with the UK is strengthened as a passageway to enter global value chains (DFID, 2017).

The present study found that the NQI institutions, other than the NAB and NFCS, were operational. The most developed institutions were the NSB and the Conformity Assessment Body in terms of certification of products and QMS certification, whereas the National Metrology Body, and testing laboratories in particular applicable to the ECAE were in the process of being strengthened through other parts of the sponsored-based capacity building projects.

The Regulatory Framework seemed to have parts in place, which were later revealed based on the introductory study work conducted rather than having observed their presence and functionality in the field during the study period. This was the same for the presence and functionality of testing laboratories other than those available at the ECAE.

In addition to the given operational needs of a facility in the food industry, the actual need for the application of specific food safety standards and their certification in Ethiopia was challenging to assess. Certainly in terms of the Certification Directorate, its lack of knowledge of the market's FSMS certification needs, certification scheme types in terms of the industry or even as preference to export markets did not assist with ensuring that it's proposed certification scheme is of a type that could meet market demand. The fact that from the sponsor's as well as the Certification Directorate's point of view to only focus on ISO 22000 as the scheme of preference, may have been ignorant to the needs of industry and therefore the obvious need for certification of food products to support economic growth through export of food for Ethiopia. The two-year period in between the two study periods was not effectively used by the Certification Directorate to determine the need of the market and to, based on this needs analysis, use the second study period to assist in building capacity towards the relevant or needed FSMS certification schemes for the country.

The results from this study suggested that different types of standards and possibly certification schemes were already prevalent in Ethiopia. The certified facilities visited, however did not reflect compliance with its certification standards, nor did it concur with the non-certified facility. Ironically, the non-certified facility, which did not utilise a consultant for its system implementation, reflected a better standard of food safety compliance than the one certified. This 'non-complying compliance' illustrates the possibility of not actually complying with the certification requirements although a status of 'compliance' has been issued.

A further interesting observation throughout the study period was that although the certification personnel had been trained and engaging in food safety activities for many years, they found it difficult to apply their knowledge of the relevant standards and their accredited QMS to develop the processes required for the FSMS certification scheme. This may have been influenced by the fact that their QMS had been developed though another sponsored capacity building project and that the thought process used to develop their certification processes was not based on their thoughts but that of an external person to the organization.

The Certification Directorate did not in the two-year study period move beyond the modification and development of processes relevant to FSMS certification. The result of the first study period showed that 88,4% of the proposed activities were not actioned, 6,2% were actioned but not completed and only 5.4% of the recommended actions were actioned and completed. This put pressure on the second study period, which was intended to move the project forward to completion, but then created a bigger challenge for the certification personnel to deal with (126 items on the recommended action item list). A number that seemingly did not sound significant, but in terms of the complexity of the project, and action items that involved major stakeholders and changes to NQI relevant activities, certainly made the figure significant relevant to the time period required to address it.

In spite of the later noted ToR issues, the benefit of the second study period was that more attention could be given to the QMS set-up and the opportunity to support the Certification Directorate with the design of a more user-friendly set of procedures and forms. More time was also spent to assess the actual competency status of the proposed pool of auditors in determining what was actually needed to reach competency of them and other certification personnel. It was realized that at this point the standard for competency of FSMS certification auditors could have been too difficult to achieve in comparison with requirements for QMS auditors. With this known difficulty, no additional effort was applied through for example food safety exercises to assist in addressing the need for improvement of competencies.

Capacity was found not to be built over the two-year study period that was needed in terms of certification personnel and facilities in the need for ensuring sustainability of the FSMS certification scheme. Knowledge based capacity was extended during the contact period of the study as the certification personnel gained a better understanding of the requirements and therefore application of the food safety related standards. This did however not assist the certification personnel with the finalization of the FSMS certification scheme and the project did not move forward where the external expert could get to a point of training on the scheme details and handing over of the QMS in order to reach the overall focus of the project.

Capacity building of this level of project is often affordable only through a sponsorship intervention. Sponsor organizations source external experts or consultants of who most are international experts, to execute the activities envisaged for such a project. The activities, objectives and deliverables for these experts are noted in a ToR relevant to the project and also in many cases to aspects or phases of a project. The ToRs of the study periods determined the road map for what had to be developed and implemented in order for the Certification Directorate to be accredited for its FSMS certification scheme within a set time frame.

The fact that this study found 70% similarity between the ToRs over the two study periods suggests that it was the presence of social rather than system-related constructs that caused the project not to move forward. Factors such as organization and people change, ownership of the responsibility to apply the recommendations given or even the complexity of the standard(s) that had to be implemented may have contributed to the fact that the project was not seen through to its finalization. Factors that are not considered and/or included in a ToR or a project plan are therefore not envisaged to be dealt with within a project of the level of complexity indicated by this capacity building project and many similar to it.

In conclusion, the capacity building project that formed the basis of this study resulted in very little, if any, progress after two years. The project achieved only the minimum outputs and never moved forward to its completion. In the author's experience, an extension of implementation time for sponsored capacity building projects is rare. Therefore, many similar projects do not see the intended results of a developing country receiving access to international markets through the trade of food.

The findings of this study thus strongly indicate that the effectiveness of donor based capacity building projects is considerably lower than the beneficiaries' needs and expectations, which then in this case did not assist in the long term overcoming implied barriers to food trade for Ethiopia.

## 5.3 Recommendations

The following recommendations are made for the Certification Directorate of the ECAE:

a. Ensure that an official ‘project champion’ be appointed to ease communication and execution of activities in line with project plans, tasks and deliverables.
b. Execute the action items on the action item list noted as part of the study 2 period outcomes.
c. Develop a third study period where the final phase of implementation of the FSMS certification scheme can be conducted, i.e. execution of certification processes in line with the completed QMS as practice runs in preparation of an accreditation assessment.

The following recommendations are made for organizations that apply sponsored capacity building projects:

a. Conduct a basic gap analysis and/or an overview of the status of the project stakeholders before setting up the ToR documents at the start of the project. This would include the determination of the actual need of the beneficiary organization as time may have lapsed since the request and the execution of a sponsored project.
b. Ensure the appointment of ‘project champions’ for ease of communication and execution of project activities within project planning timelines.
c. Involve external or international experts to participate in the development of the ToR of projects.
d. Incorporate in the project management the impact of transformation and change within the project period, and intervene when required to support experts with the execution of tasks as well as the changing of project outputs in line with this management factor.
e. Coordinate with experts and different parts of projects over the life cycle of a sponsored programme to prevent duplication and to ease integration of expert activities and work conducted.

## 5.4 Future research

Future research in support of capacity building projects should comprise the following:

a. The determination of actual successes of the implementation of capacity building projects at the level of the TBT support office of the WTO to ensure effective and productive financial support to such projects.
b. The impact of transformation and change on organizations and personnel of the organization receiving sponsored capacity building projects. The concept of resistance to change in achieving project goals in food safety management.
c. The impact of unwillingness or unable factors to accept different points of view and conflict towards points of view consulted on in the process of change for the purpose of reaching a project objective and specific deliverable.
d. The effectiveness of accredited FSMS certification in reducing the risk food-borne illness and injury to the consumer.
e. The impact of an NFCS to reduce the fragmented approach of the regulatory framework of governments towards food control.
f. The impact of the various FSMS certification schemes on the production of safe food, possible technical barriers to trade and actual safety of the consumer.
g. The impact of standards in setting achievable requirements for bodies that operate certification activities towards food safety. Are the requirements of personnel too strict and does the strictness actually benefit the execution of the audit and also the industry?

## 5.5 References

Department for International Development (DFID). (2017) *Economic Development Strategy: Prosperity, poverty and meeting global challenges,* London: DFID.

ISO 22000. (2005) *Food safety management systems – Requirements for any organization in the food chain,* Geneva: ISO.

ISO/TS 22003. (2007) *Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems*, Geneva: ISO.

# ANNEXURES

**Annexure 2.1:** Principles of an NFCS as adopted from Codex (2013)

| Principle | Activity | Short description of what the activity involves |
|---|---|---|
| **Principle 1** | Protection of consumers | The design, implementation and maintenance should be focused to protect the consumer. During conflict with other interests, precedence should be given to protect the health of the consumer. |
| **Principle 2** | The whole food chain approach | Should include the entire food chain from primary production to consumption. |
| **Principle 3** | Transparency | Should be transparent and open to scrutiny by all stakeholders. Should still respect legal requirements in protecting confidential information. Should apply to all participants in the food chain achieved through clear documentation and communication. |
| **Principle 4** | Roles and responsibilities | All participants should have specific and clearly defined roles and responsibilities. Food business operators remain primarily responsible for the management of food safety of their products and to comply with its relevant requirements. National government or the competent authority are responsible to establish and maintain up-to-date legal requirements and to operate the system effectively. Consumers are responsible to manage food safety risks under their control and in accordance with the relevant information supplied to them. Academics and scientific institutions play a role as a source of expertise in supporting a risk-based and scientific foundation of the system. |
| **Principle 5** | Consistency and impartiality | All aspects should be applied consistently and impartially. The competent authority and all participants should be free of improper or undue influence or conflict of interest. |

| Principle | Activity | Short description of what the activity involves |
|---|---|---|
| Principle 6 | Risk-based, science-based and evidence-based decision-making | The competent authority should make decisions based on scientific information, evidence and/or risk analysis principles. The risk analysis principles should be in line with the Codex Working Principles for Risk Analysis for Food Safety for Application by Governments and policies developed by the World Organization for Animal Health. |
| Principle 7 | Cooperation and coordination between multiple competent authorities | The competent authorities should operate in a cooperative and coordinated manner through clearly defined roles and responsibilities and the effective application of resources to minimise duplication and/or gaps and to facilitate information exchange. |
| Principle 8 | Preventive measures | Prevent and when required respond to food safety incidents and should therefore encompass the core elements of prevention, intervention and response. |
| Principle 9 | Self-assessment and review procedures | Should have the capacity and capability to undergo continuous improvement and needs to include mechanisms to evaluate if the system is able to achieve its objectives. |

| Principle | Activity | Short description of what the activity involves |
|---|---|---|
| **Principle 10** | Recognition of other systems (including equivalence) | Competent authorities should recognise that the system or its components are capable of meeting the same objectives even though they might be designed and structured differently. This recognition may apply at the national and international level. The system should provide for the concept of recognition of systems, including equivalence. The Codex Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems as well as the Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems should be applied. |
| **Principle 11** | Legal foundation | The government of the country should have a fundamental legal structure in place to enable the establishment of food laws and competent authorities. This is required for the development, establishment, implementation, maintenance and enforcement of the system. |
| **Principle 12** | Harmonization | The competent authority should, in the design and the application of the system, consider Codex standards, recommendations and guidelines to ensure the protection of the health of the consumer and to ensure fair practices in the food trade. The consideration of standards, recommendations or guidelines from other international intergovernmental organizations may also be useful (when open to other countries). |
| **Principle 13** | Resources | Should have sufficient resources to enable the system to meet its objectives. |

**Annexure 3.1:** Summary of the contents of the mandatory international standards Information applied directly from ISO/IEC 17021 (2011) and ISO/TS 22003 (2007) The mandatory international standards included the review to be conducted against the following requirements:

| ISO/IEC 17021 (2011) | ISO/TS 22003 (2007) |
|---|---|
| Principles<br>• General<br>• Impartiality<br>• Competence<br>• Responsibility<br>• Openness<br>• Confidentiality<br>• Responsiveness to complaints<br><br>General requirements<br>• Legal and contractual matters<br>  ○ Legal responsibility<br>  ○ Certification agreement<br>  ○ Responsibility for certification decisions<br>• Management of impartiality<br>• Liability and financing<br><br>Structural requirements<br>• Organizational structure and top structure<br>• Committee for safeguarding impartiality<br><br>Resource requirements<br>• Competence of management and personnel<br>  ○ General considerations<br>  ○ Determination of competence criteria<br>  ○ Evaluation process<br>  ○ Other considerations<br>• Personnel involved in the certification activities<br>• Use of individual external auditors and external technical experts<br>• Personnel records<br>• Outsourcing<br><br>Information requirements<br>• Publicly accessible information<br>• Certification documents | Principles<br><br>General requirements<br>• General<br>• Management of impartiality<br><br>Structural requirements<br><br>Resource requirements<br>• Competence of management and personnel<br>• Personnel involved in the certification activities<br>  ○ General<br>  ○ Personnel carrying out contract review<br>  ○ Personnel granting certification<br>  ○ Auditors<br>  ○ Technical experts<br>  ○ Selection of the audit team<br>• Use of individual external auditors and external technical experts<br>• Personnel records<br>• Outsourcing<br><br>Information requirements<br><br>Process requirements<br>• General requirements<br>• Initial audit and certification<br>  ○ Application<br>  ○ Application review<br>  ○ Initial certification audit<br>  ○ Initial certification audit conclusions<br>  ○ Information for granting initial certification<br>• Surveillance activities<br>• Recertification<br>• Special audits<br>• Suspending, withdrawing or reducing the scope of certification<br>• Appeals |

| ISO/IEC 17021 (2011) | ISO/TS 22003 (2007) |
|---|---|
| • Directory of certified clients<br>• Reference to certification and use of marks<br>• Confidentiality<br>• Information exchange between a CB and its clients<br>  ○ Information on the certification activity and requirements<br>  ○ Notice of changes by a CB<br>  ○ Notice of changes by a client<br><br><u>Process requirements</u><br>• General requirements<br>  ○ Audit programme<br>  ○ Audit plan<br>  ○ Audit team selection and assignments<br>  ○ Determining audit time<br>  ○ Multi-site sampling<br>  ○ Communication of audit team tasks<br>  ○ Communication concerning audit team members<br>  ○ Communication of audit plan<br>  ○ Conducting on-site audits<br>  ○ Audit report<br>  ○ Cause analysis of nonconformities<br>  ○ Effectiveness of corrections and corrective actions<br>  ○ Additional audits<br>  ○ Certification decision<br>  ○ Actions prior to making a decision<br>• Initial audit and certification<br>  ○ Application<br>  ○ Application review<br>  ○ Initial certification audit<br>  ○ Initial certification audit conclusions<br>  ○ Information for granting initial certification<br>• Surveillance activities<br>  ○ General<br>  ○ Surveillance audit<br>  ○ Maintaining certification<br>• Recertification<br>  ○ Recertification audit planning<br>  ○ Recertification audit | • Complaints<br>• Records of applicants and clients<br><br><u>Management system requirements for CBs</u><br><br><u>Annex A</u> (normative) Classification of food chain categories<br><br><u>Annex B</u> (informative) Minimum audit time |

| ISO/IEC 17021 (2011) | ISO/TS 22003 (2007) |
|---|---|
| • Special audits<br>  ○ Extension to scope<br>  ○ Short-notice audits<br>• Suspending, withdrawing or reducing the scope of certification<br>• Appeals<br>• Complaints<br>• Records of applicants and clients<br><br>Management system requirements for CBs<br>Options<br>• Option 1: Management system requirements in accordance with ISO 9001<br>  ○ General<br>  ○ Scope<br>  ○ Customer focus<br>  ○ Management review<br>• Option 2: General management system requirements<br>  ○ General<br>  ○ Management system manual<br>  ○ Control of documents<br>  ○ Control of records<br>  ○ Management review<br>  ○ Internal audits<br>  ○ Corrective actions<br>  ○ Preventive actions<br><br>Annex A (normative) Required knowledge and skills<br><br>Annex B (informative) Possible evaluation methods<br><br>Annex C (informative) Example of a process flow for determine and maintaining competence<br><br>Annex D (informative) Desired personal behaviours<br><br>Annex E (informative) Third-party audit and certification processes<br><br>Annex F (informative) considerations for the audit programme, scope or plan | |

**Annexure 3.2:** Reference to the use of the selected IAF mandatory, information and guidance documents relevant to the study project

The relevant supporting information applied during the review included the following:

| IAF Mandatory Documents | IAF Guidance or Information Documents |
|---|---|
| MD1:2007 – Certification of Multiple Sites Based on Sampling (Issue 1, version 2)<br><br>MD2:2007 – Transfer of Accredited Certification of Management Systems (Issue 1)<br><br>MD3:2008 – Advanced Surveillance and Recertification Procedures (Issue 1)<br><br>MD4:2008 – The use of Computer Assisted Auditing Techniques ('CAAT') for Accredited Certification of Management Systems (Issue 1)<br><br>MD5:2009 – Duration of QMS and EMS Audits (Issue 1)<br><br>MD7:2010 – Harmonization of Sanctions to be applied to Conformity Assessment Bodies (Issue 1, Version 2) | Joint IAF-ISO Communiqué, Transition to ISO/IEC 17021:2011 (February 2011)<br><br>ID1:2010 – QMS Scopes of Accreditation (Issue 1)<br><br>ID2:2011 – The Transition of Management System Accreditation to ISO/IEC 17021:2011 from ISO/IEC 17021:2006 (Issue 1)<br><br>GD2:2005 – The Application of ISO/IEC Guide 62:1996 General Requirements for Bodies Operating Assessment and Certification/registration of Quality Systems (Issue 4) |

**Annexure 3.3:** Normative criteria for auditing knowledge and skills of certification personnel

Applied directly from Annex A of ISO/IEC 17021 (2011).

| Certification functions / Knowledge and skills | Conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time | Reviewing audit reports and making certification decisions | Auditing | Leading the audit team |
|---|---|---|---|---|
| Knowledge of business management practices | | | X | X |
| Knowledge of audit principles, practices and techniques | | X | X+ | X+ |
| Knowledge of specific management system standards or normative documents | X | X | X+ | X+ |
| Knowledge of CB processes | X | X | X | X |
| Knowledge of client business sector | X | X | X+ | X+ |
| Knowledge of client products, processes and organization | X | | X | X |
| Language skills appropriate to all levels within the client organization | | | X | X |
| Note-taking and report-writing skills | | | X | X |
| Presentation skills | | | X | X+ |

| Certification functions / Knowledge and skills | Conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time | Reviewing audit reports and making certification decisions | Auditing | Leading the audit team |
|---|---|---|---|---|
| Interviewing skills | | | X | X |
| Audit management skills | | | X | X+ |
| For knowledge of client products, processes and organization, where a team is performing the task, the expertise needs to exist within that team or could be provided by a technical expert. Where any audit is conducted by a team, the level of skills required should be held within the team as a whole and not by every individual member of the team.<br>The team leader of a combined or integrated audit should have an in-depth knowledge of at least one of the standards and is required to be aware of the other standards used for that particular audit.<br>NOTE: Risk and complexity are other considerations when deciding the level of expertise needed for any of these functions. | | | | |

These criteria are to be defined for the specific certification functions listed.

**X** means the CB shall define the criteria and depth of knowledge and skills.

**X+** indicates a need for deeper knowledge and skills.

**Annexure 3.4:** Education, food safety training, audit training, work experience and audit experience of certification personnel involved in food safety management system certification activities

Summarized directly from the contents of ISO/TS 22003 (2007)

| Requirement | Application review personnel | Certification decision personnel | Auditor | Technical expert |
|---|---|---|---|---|
| **Education** | | | | |
| Secondary education | X | | | |
| Post-secondary education including general microbiology and general chemistry | | X | X | |
| Post-secondary education that includes courses in food chain industry category in which the audit will be conducted, i.e.<br>a) Category C, D, E, F, G & H – food microbiology, food processing fundamentals, food chemistry and food analysis<br>b) Category B – crop production<br>c) Category A & F – animal production<br>d) Category I, J, K, L & M – science or engineering related to the discipline | | X | X | |
| Post-secondary education in food chain industry sector, processes to be audited or food safety hazards applicable to the sector | | | | X |

| Requirement | Application review personnel | Certification decision personnel | Auditor | Technical expert |
|---|---|---|---|---|
| **Food safety training** | | | | |
| HACCP principles | X | X | X | |
| Hazard assessment | X | X | X | |
| Hazard analysis | X | X | X | |
| Food safety management principles | X | X | X | |
| Prerequisite programmes (PRPs) | X | X | X | |
| ISO 22000 standard | X | | | |
| **Audit training** | | | | |
| Training on audit processes based on ISO 19011 | X | | | |
| Audit techniques based on ISO 19011 | | X | X | |
| ISO 22000 standard | | X | X | |
| **Work experience** | | | | |
| First qualification<br>Five years full-time work in the food chain category related industry which includes two years quality or food safety functions with food production or manufacturing, retailing, inspection or enforcement or equivalent | | X | X | |
| Post-secondary education<br>As above, but can reduce total work experience to four years | | X | X | |

| Requirement | Application review personnel | Certification decision personnel | Auditor | Technical expert |
|---|---|---|---|---|
| Have work experience in the expert's technical area | | | | X |
| **Audit experience** | | | | |
| First qualification<br>Within the last three years at least 12 FSMS audit days in at least four organizations under the leadership of a qualified auditor | | | X | |
| Extension to new category<br>a) Education competencies in the category<br>b) Food safety related training in the category<br>c) Six months work experience in the category<br>OR<br>a) Four FSMS audits under supervision of qualified auditor in the category | | | X | |
| Maintaining auditing<br>a) Minimum of five external audits per year, including two FSMS audits<br>b) Minimum of four FSMS on-site external audits<br>OR<br>a) 10 FSMS audit days per year | | | X | |

| Requirement | Application review personnel | Certification decision personnel | Auditor | Technical expert |
|---|---|---|---|---|
| **Competencies (ability to apply knowledge and skills recorded for each category and sector)** | | | | |
| Classification of applicants in food chain category and sectors | X | | | |
| Assessment of applicant products, processes and practices | X | | | |
| Deployment of FSMS auditor competencies and requirements | X | | | |
| Determination of audit time and duration requirements | X | | | |
| CB policies and procedures relating to application review | X | | | |
| Audit principles, procedures and techniques<br>(+ 13 requirements of annexure 3.6) | | | X | |
| Management system and reference documents<br>(+ detail in annexure 3.6) | | | X | |
| Organizational situations<br>(+ detail in annexure 3.6) | | | X | |
| Applicable laws, regulations and other requirements relevant to the discipline<br>(+ detail in annexure 3.6) | | | X | |
| Ability to apply terminology, knowledge and skills for (a) to (k): | | | X | |

| Requirement | Application review personnel | Certification decision personnel | Auditor | Technical expert |
|---|---|---|---|---|
| a) Principles of HACCP | | X | X | |
| b) Relevant PRPs to the food chain category | | X | X | |
| c) Identification of food safety hazards | | X | X | |
| d) Methodologies, used for determination, implementation and management of control measures (PRPs, operational PRPs, CCPs) and ability to assess the effectiveness of selected control measures | | X | X | |
| e) Correction and corrective actions to be taken with regard to food safety matters | | X | X | |
| f) Assessment of potential food safety hazards linked to the food supply chain | | X | X | |
| g) Evaluation of the relevance of applicable PRPs and establishing or selecting appropriate evaluation method or guide for PRPs in the category | | | X | |
| h) Laws and regulations relevant to food safety | | X | X | |
| i) Products, processes and practices of the specific | | X | X | |

| Requirement | Application review personnel | Certification decision personnel | Auditor | Technical expert |
|---|---|---|---|---|
| category | | | | |
| j) ISO 22000 requirements | | X | X | |
| k) Relevant food safety standards | | X | X | |
| l) Assessment and review of an audit report for accuracy and completeness | | X | | |
| m) Assessment and review of the effectiveness of corrective actions | | X | | |
| Demonstrated expertise in the expert's technical area | | | | X |

**Annexure 3.5:** Food chain categories

Applied directly from Annex A of ISO/TS 22003 (2007)

| Category code | Categories | Examples of sectors |
|---|---|---|
| **A** | Farming 1 (Animals) | Animals, fish, egg production, milk production, beekeeping, fishing, hunting, trapping |
| **B** | Farming 2 (Plants) | Fruits, vegetables, grain, spices, horticultural products |
| **C** | Processing 1 (Perishable animal products) Including all activities after farming, i.e. slaughtering | Meat, poultry, eggs, dairy and fish products |
| **D** | Processing 2 (Perishable vegetal products) | Fresh fruits and fresh juices, preserved fruits, fresh vegetables, preserved vegetables |
| **E** | Processing 3 (Products with long shelf life at ambient temperature) | Canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt |
| **F** | Feed production | Animal feed, fish feed |
| **G** | Catering | Hotels, restaurants |
| **H** | Distribution | Retail outlets, shops, wholesalers |
| **I** | Services | Water supply, cleaning, sewage, waste disposal, development of product, process and equipment, veterinary services |
| **J** | Transport and storage | Transport and storage |
| **K** | Equipment manufacturing | Process equipment, vending machines |
| **L** | Biochemical manufacturing | Additives, vitamins, pesticides, drugs, fertilizers, cleaning agents, biocultures |

| Category code | Categories | Examples of sectors |
|---|---|---|
| **M** | Packaging material manufacturing | Packaging material |

**Annexure 3.6:** Knowledge and skills required for auditors

Summarized directly from ISO 19011 (2011) and ISO/TS 22003 (2007).

| **ISO 19011**<br>NOTE: ISO/TS 22003 referred to the 2002 version of ISO 19011 for these requirements. The 2011 version of ISO 19011 was, however, used due to it being more relevant in terms of the validity of the standard | **ISO/TS 22003** |
|---|---|
| **1 Generic knowledge and skills of management system auditors** | |
| a) Audit principles, procedures and methods | |
| • Apply audit principles, procedures, and methods | • Apply audit principles, procedures, and techniques |
| • Plan and organize the work effectively | • Plan and organize the work effectively |
| • Conduct the audit within the agreed time schedule | • Conduct the audit within the agreed time schedule |
| • Prioritize and focus on matters of significance | • Prioritize and focus on matters of significance |
| • Collect information through effective interviewing, listening, observing and reviewing documents, records and data | • Collect information through effective interviewing, listening, observing and reviewing documents, records and data |
| • Understand and consider the experts' opinions | – |
| • Understand the appropriateness and consequences of using sampling techniques for auditing | • Understand the appropriateness and consequences of using sampling techniques for auditing |
| • Verify the relevance and accuracy of collected information | • Verify the relevance and accuracy of collected information |
| • Confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions | • Confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions |
| • Assess those factors that may affect the reliability of the audit findings and conclusions | • Assess those factors that may affect the reliability of the audit findings and conclusions |

| ISO 19011<br>NOTE: ISO/TS 22003 referred to the 2002 version of ISO 19011 for these requirements. The 2011 version of ISO 19011 was, however, used due to it being more relevant in terms of the validity of the standard | ISO/TS 22003 |
|---|---|
| • Use work documents to record audit activities | • Use work documents to record audit activities |
| • Document audit findings and prepare appropriate audit reports | • Prepare audit reports |
| • Maintain the confidentiality and security of information, data, documents and reports | • Maintain the confidentiality and security of information |
| • Communicate effectively, orally and in writing (either personally or through the use of interpreters and translators) | • Communicate effectively, either through personal linguistic skills or through an interpreter |
| • Understand the types of risks associated with auditing | – |
| b) Management system and reference documents | |
| • Management system standards or other documents used as audit criteria | • Food safety management system standards, applicable procedures or other management system documents used as audit criteria |
| • The application of management system standards by the auditee and other organizations, as appropriate | • The application of management systems to different organizations |
| • Interaction between the components of the management system | • Interaction between the components of the management system |
| • Recognition of the hierarchy of reference documents | • Recognition of differences between, and the priority of, the reference documents |
| • Application of the reference documents to different audit situations | • Application of the reference documents to different audit situations |

| ISO 19011<br>NOTE: ISO/TS 22003 referred to the 2002 version of ISO 19011 for these requirements. The 2011 version of ISO 19011 was, however, used due to it being more relevant in terms of the validity of the standard | ISO/TS 22003 |
|---|---|
| – | • Information systems and technology for authorization, security, distribution and control of documents, data and records |
| c) Organizational context | |
| • Organizational types, governance, size, structure, functions and relationships | • Organizational size, structure, functions and relationships |
| • General business and management concepts, processes and related terminology, including planning, budgeting and management of personnel | • General business processes and related terminology |
| • Cultural and social aspects of the auditee | • Cultural and social aspects of the auditee |
| d) Applicable legal and contractual requirements and other requirements that apply to the auditee | |
| • Laws and regulations and their governing agencies | • Local, regional and national codes, laws and regulations |
| • Basic legal terminology | – |
| • Contracting and liability | • Contracts and agreements |
| - | • International treaties and conventions |
| - | • Other requirements to which the organization subscribes |
| **2 Discipline and sector-specific knowledge and skills of management system auditors** | |
| • Discipline-specific management system requirements and principles, and their application | See annexure 3.4 |

| ISO 19011<br>NOTE: ISO/TS 22003 referred to the 2002 version of ISO 19011 for these requirements. The 2011 version of ISO 19011 was, however, used due to it being more relevant in terms of the validity of the standard | ISO/TS 22003 |
|---|---|
| • Legal requirements relevant to the discipline and sector, such that the auditor is aware of the requirements specific to the jurisdiction and the auditee's obligations, activities and products<br>• Requirements of interested parties relevant to the specific discipline<br>• Fundamentals of the discipline and the application of business and technical discipline-specific methods, techniques, processes and practices, sufficient to enable the auditor to examine the management system and generate appropriate audit findings and conclusions<br>• Discipline-specific knowledge related to the particular sector, nature of operations or workplace being audited, sufficient for the auditor to evaluate the auditee's activities, processes, and products (goods and services)<br>• Risk management principles, methods and techniques relevant to the discipline and sector, such that the auditor can evaluate and control the risks associated with the audit programme | |

| ISO 19011<br>NOTE: ISO/TS 22003 referred to the 2002 version of ISO 19011 for these requirements. The 2011 version of ISO 19011 was, however, used due to it being more relevant in terms of the validity of the standard | ISO/TS 22003 |
|---|---|
| **3 Generic knowledge and skills of an audit team leader** | |
| a) Balance the strengths and weaknesses of the individual audit team members<br>b) Develop a harmonious working relationship among the audit team members<br>c) Manage the audit process, including:<br>• Planning the audit and making effective use of resources during the audit<br>• Managing the uncertainty of achieving audit objectives<br>• Protecting the health and safety of the audit team members during the audit, including ensuring compliance of the auditors with the relevant health, safety and security requirements<br>• Organizing and directing the audit team members<br>• Providing direction and guidance to auditors-in-training<br>• Preventing and resolving conflicts, as necessary<br>d) Represent the audit team in communications with the person managing the audit programme, audit client and auditee<br>e) Lead the audit team to reach the audit conclusions | No specified requirements from ISO/TS 22003. ISO 19011 applies. |

| ISO 19011<br>NOTE: ISO/TS 22003 referred to the 2002 version of ISO 19011 for these requirements. The 2011 version of ISO 19011 was, however, used due to it being more relevant in terms of the validity of the standard | ISO/TS 22003 |
|---|---|
| f) Prepare and complete the audit report | |
| **4 Knowledge and skills for auditing management systems for multiple disciplines** | |
| • Competence necessary to audit at least one of the management system disciplines and an understanding of the interaction and synergy between the different management systems<br>• Audit team leaders – understand the requirements of each of the management system standards and recognize the limits of their knowledge and skills in each of the disciplines | No specified requirements from ISO/TS 22003. ISO 19011 applies. |
| **5 Audit team(s)** | |
| Audit team requirements are not specified but audit team leaders are:<br>• Have to acquire additional audit experience to develop knowledge and skills described above | Competencies in the application of PRPs and HACCP in the food chain category |

**Annexure 3.7:** Personal behaviour and the principles of auditing

Auditors should possess the personal qualities to enable them to act in accordance with the principles of auditing. Summarized directly from ISO 19011 (2011).

| **Personal behaviour** |
|---|
| a) Ethical, i.e. fair, truthful, sincere, honest and discreet<br>b) Open-minded, i.e. willing to consider alternative ideas or points of view<br>c) Diplomatic, i.e. tactful in dealing with people<br>d) Observant, i.e. actively observing physical surroundings and activities<br>e) Perceptive, i.e. aware of and able to understand situations<br>f) Versatile, i.e. able to readily adapt to different situations<br>g) Tenacious, i.e. persistent and focused on achieving objectives<br>h) Decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis<br>i) Self-reliant, i.e. able to act and function independently while interacting effectively with others<br>j) Acting with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation<br>k) Open to improvement, i.e. willing to learn from situations, and striving for better audit results<br>l) Culturally sensitive, i.e. observant and respectful to the culture of the auditee<br>m) Collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel |
| **Principles of auditing** |
| a) Integrity – the foundation of professionalism<br>b) Fair presentation – the obligation to report truthfully and accurately<br>c) Due professional care – the application of diligence and judgement in auditing<br>d) Confidentiality – security of information<br>e) Independence – the basis of the impartiality of the audit and objectivity of the audit conclusions<br>f) Evidence-based approach – the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process |

**Annexure 3.8:** Summary of the contents of ISO 22000 (2005) and ISO/TS 22002-1 (2009)

| ISO 22000 (2005) | | ISO/TS 22002-1 | |
|---|---|---|---|
| **Clause number** | **Clause title** | **Clause number** | **Clause title** |
| 4 | Food safety management system | 4 | Construction and layout of buildings |
| 4.1 | General requirements | 4.1 | General requirements |
| 4.2 | Documentation requirements | 4.2 | Environment |
| 4.2.1 | General | 4.3 | Locations of establishments |
| 4.2.2 | Control of documents | 5 | Layout of premises and workspace |
| 4.2.3 | Control of records | 5.1 | General requirements |
| 5 | Management responsibility | 5.2 | Internal design, layout and traffic patterns |
| 5.1 | Management commitment | 5.3 | Internal structures and fittings |
| 5.2 | Food safety policy | 5.4 | Location of equipment |
| 5.3 | Food safety management system planning | 5.5 | Laboratory facilities |
| 5.4 | Responsibility and authority | 5.6 | Temporary or mobile premises and vending machines |
| 5.5 | Food safety team leader | 5.7 | Storage of food, packaging materials, ingredients and non-food chemicals |
| 5.6 | Communication | 6 | Utilities – air, water, energy |
| 5.6.1 | External communication | 6.1 | General requirements |
| 5.6.2 | Internal communication | 6.2 | Water supply |
| 5.7 | Emergency preparedness and response | 6.3 | Boiler chemicals |
| 5.8 | Management review | 6.4 | Air quality and ventilation |
| 5.8.1 | General | 6.5 | Compressed air and other gasses |
| 5.8.2 | Review input | 6.6 | Lighting |
| 5.8.3 | Review output | 7 | Waste disposal |
| 6 | Resource management | 7.1 | General requirements |
| 6.1 | Provision of resources | 7.2 | Containers for waste and inedible or hazardous substances |
| 6.2 | Human resources | 7.3 | Waste management and removal |
| 6.2.1 | General | 7.4 | Drains and drainage |
| 6.2.2 | Competence, awareness and training | 8 | Equipment suitability, cleaning and maintenance |
| 6.3 | Infrastructure | 8.1 | General requirements |
| 6.4 | Work environment | 8.2 | Hygiene design |
| 7 | Planning and realization of safe products | 8.3 | Product contact surfaces |

| ISO 22000 (2005) | | ISO/TS 22002-1 | |
|---|---|---|---|
| 7.1 | General | 8.4 | Temperature control and monitoring equipment |
| 7.2 | Prerequisite programmes (PRPs) | 8.5 | Cleaning plant, utensils and equipment |
| 7.2.1 | *No title* | 8.6 | Preventive and corrective maintenance |
| 7.2.2 | *No title* | 9 | Management of purchased materials |
| 7.2.3 | *No title* | 9.1 | General requirements |
| 7.3 | Preliminary steps to enable hazard analysis | 9.2 | Selection and management of suppliers |
| 7.3.1 | General | 9.3 | Incoming material requirements (raw/ingredients/packaging) |
| 7.3.2 | Food safety team | 10 | Measures for prevention of cross-contamination |
| 7.3.3 | Product characteristics | 10.1 | General requirements |
| 7.3.3.1 | Raw materials, ingredients and product-contact materials | 10.2 | Microbiological cross-contamination |
| 7.3.3.2 | Characteristics of end products | 10.3 | Allergen management |
| 7.3.4 | Intended use | 10.4 | Physical contamination |
| 7.3.5 | Flow diagrams, process steps and control measures | 11 | Cleaning and sanitizing |
| 7.3.5.1 | Flow diagrams | 11.1 | General requirements |
| 7.3.5.2 | Description of process steps and control measures | 11.2 | Cleaning and sanitizing agents and tools |
| 7.4 | Hazard analysis | 11.3 | Cleaning and sanitizing programmes |
| 7.4.1 | General | 11.4 | Cleaning in place (CIP) systems |
| 7.4.2 | Hazard identification and determination of acceptable levels | 11.5 | Monitoring sanitation effectiveness |
| 7.4.2.1 | *No title* | 12 | Pest control |
| 7.4.2.2 | *No title* | 12.1 | General requirements |
| 7.4.2.3 | *No title* | 12.2 | Pest control programmes |
| 7.4.3 | Hazard assessment | 12.3 | Preventing access |
| 7.4.4 | Selection and assessment of control measures | 12.4 | Harbourage and infestations |
| 7.5 | Establishing the operational prerequisite programmes (PRPs) | 12.5 | Monitoring and detection |
| 7.6 | Establishing the HACCP plan | 12.6 | Eradication |
| 7.6.1 | HACCP plan | 13 | Personnel hygiene and employee facilities |
| 7.6.2 | Identification of critical control points (CCPs) | 13.1 | General requirements |

| ISO 22000 (2005) | | ISO/TS 22002-1 | |
|---|---|---|---|
| 7.6.3 | Determination of critical limits for critical control points | 13.2 | Personnel hygiene facilities and toilets |
| 7.6.4 | System of the monitoring of critical control points | 13.3 | Staff canteens and designated eating areas |
| 7.6.5 | Actions when monitoring results exceed critical limits | 13.4 | Workwear and protective clothing |
| 7.7 | Updating of preliminary information and documents specifying the PRPs and the HACCP plan | 13.5 | Health status |
| 7.8 | Verification planning | 13.6 | Illness and injuries |
| 7.9 | Traceability system | 13.7 | Personal cleanliness |
| 7.10 | Control of nonconformity | 13.8 | Personal behaviour |
| 7.10.1 | Corrections | 14 | Rework |
| 7.10.2 | Corrective actions | 14.1 | General requirements |
| 7.10.3 | Handling of potentially unsafe products | 14.2 | Storage, identification and traceability |
| 7.10.3.1 | General | 14.3 | Rework usage |
| 7.10.3.2 | Evaluation for release | 15 | Product recall procedures |
| 7.10.3.3 | Disposition of nonconforming products | 15.1 | General requirements |
| 7.10.4 | Withdrawals | 15.2 | Product recall requirements |
| 8 | Validation, verification and improvement of the food safety management system | 16 | Warehousing |
| 8.1 | General | 16.1 | General requirements |
| 8.2 | Validation of control measure combinations | 16.2 | Warehousing requirements |
| 8.3 | Control of monitoring and measuring | 16.3 | Vehicles, conveyances, and containers |
| 8.4 | Food safety management system verification | 17 | Product information and consumer awareness |
| 8.4.1 | Internal audit | 18 | Food defence, biovigilance, and bioterrorism |
| 8.4.2 | Evaluation of individual verification results | | |
| 8.4.3 | Analysis of results of verification activities | | |
| 8.5 | Improvement | | |
| 8.5.1 | Continual improvement | | |
| 8.5.2 | Updating the food safety management system | | |

**Annexure 3.9:** Summary of the results of the documentation review conducted under activity 2

ISO/IEC 17021 (2011) was used as basis for this document and the document review. The clauses that have been updated with new requirements are marked in **red**. Additional requirements stipulated by ISO/TS 22003 (2007) are marked in ***blue***.

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| **4 Principles** | |
| **4.1 General** | |
| 4.1.1 | No particular document given and no particular statements made. |
| 4.1.2 | The Quality Manual mentioned the list under 4.1.3, however, no detail was supplied on how the commitment to impartiality, competence, responsibility, openness, confidentiality and responsiveness to complaints are to be carried out.<br>***Comments/actions on-site:***<br>*More information on the aspects of 4.1.3 was added where possible. The certification personnel are to review the information included and add information where it is lacking.* |
| 4.1.3 | |
| **4.2 Impartiality** | |
| 4.2.1 | No particular document given and no particular statements made. |
| 4.2.2 | ***Comments/actions on-site:***<br>*Reference to this aspect was placed into the reviewed certification agreement.* |
| 4.2.3 | |
| 4.2.4 | |
| **4.3 Competence** | |
| - | No particular document given and no particular statements made. |
| **4.4 Responsibility** | |
| 4.4.1 | No particular document given and no particular statements made. |
| 4.4.2 | ***Comments/actions on-site:***<br>*Reference to this aspect was placed into the reviewed certification agreement.* |
| **4.5 Openness** | |
| 4.5.1 | No particular document given and no particular statements made. |
| 4.5.2 | ***Comments/actions on-site:***<br>*Reference to this aspect was placed into the reviewed certification agreement.* |
| **4.6 Confidentiality** | |
| - | No particular document given and no particular statements made.<br>***Comments/actions on-site:***<br>*Reference to this aspect was placed into the reviewed certification agreement.* |
| **4.7 Responsiveness to complaints** | |
| - | No particular document given and no particular statements made.<br>***Comments/actions on-site:***<br>*Reference to this aspect was placed into the reviewed certification agreement.* |
| **5 General requirements** | |
| **5.1 Legal and contractual matters** | |
| 5.1.1 | Legal entity statements made in the Quality Manual. |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| 5.1.2 | No document given.<br>***Comments/actions on-site:***<br>*A copy of the certification agreement – OF/CD/1.33 was given during the on-site visit.*<br>*The agreement was identified by a prefix indicating a form. This was questioned.*<br>*The copy given was perceived to be badly written and not in the expected format as required for legal documents. The entire agreement was reviewed and retyped into a more appropriate and correct format and was updated to reflect all the possible requirements needed to indicate compliance with the standards and to further support any possible liability claims due to certification and the lack of stating requirements in a legal agreement between both parties.* |
| 5.1.3 | A certification decision committee was already established. |
| **5.2 Management of impartiality** | |
| ***Extra reqmt*** | **Comments**<br>Direct wording from the standard was added to the impartiality policy. The 'how' it will be ensured is not stated and may need to be reviewed when on-site. |
| 5.2.1 | **Comments**<br>ECAE Cert Impartiality Policy – OF/CD/1.52<br>The policy statement identification indicates it being a form. This is questioned as it is a policy and not a form. The documentation structure needs to allow for documents such as policies, which are seen as part of a group of unique documents.<br>The policy was also included in the Quality Manual.<br>***Comments/actions on-site:***<br>*Information was added to the certification agreement.*<br>*No work was done on the policy statement.* |
| 5.2.2<br>5.2.3<br>5.2.4<br>5.2.5<br>5.2.6<br>5.2.7<br>5.2.8<br>5.2.9<br>5.2.10<br>5.2.11<br>5.2.12<br>5.2.13 | No particular document given.<br>***Comments/actions on-site:***<br>*Information was added to the certification agreement.* |
| **5.3 Liability and financing** | |
| 5.3.1<br>5.3.2 | No particular document given and no particular statements made.<br>***Comments/actions on-site:***<br>*Discussions took place and recommendations made to deal with this requirement. Placed in action plan* |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| **6 Structural requirements** | |
| **6.1 Organizational structure and top management** | |
| 6.1.1 | No particular document provided and no particular statements made. |
| 6.1.2 | ***Comments/actions on-site:*** |
| 6.1.3 | *An organizational chart was available during the on-site visit.*<br>*Particular responsibility information (6.1.2) was included in the Quality Manual as it was not identified as being documented in any other document(s) presented.* |
| **6.2 Committee for safeguarding impartiality** | |
| 6.2.1 | **Comments** |
| 6.2.2 | Impartiality committee member major responsibilities – MR/CD/1.6 |
| 6.2.3 | 1. The header includes reference to ISO/IEC 17021, however, not to ISO/TS 22003. FSMS was added in brackets only.<br>2. Not all the particular requirements of this clause are reflected by the document supplied. The detail of the document, the requirements of the standards and the actual activity and functionality of this committee would need to be discussed during the on-site visit.<br>3. The information included under the competence requirements of this document is questioned in terms of the possible members and would also need to be discussed during the on-site visit.<br>***Comments/actions on-site:***<br>*No work was done on this document.* |
| **7 Resource requirements** | |
| **7.1 Competence of management and personnel** | |
| ***Extra reqmt*** | The unique requirements of this clause need to be determined by the on-site activities. Limited documents on personnel requirements information were included for the document review and those included are most probably not the only documents. The review of these aspects would be more effective once on-site. |
| **7.1.1**<br>**7.1.2**<br>**7.1.3**<br>**7.1.4.1**<br>**7.1.4.2** | **Comments**<br>Personnel competence evaluation and development procedure – OP/CD/1.5<br>1. This was the only document (other than some competence criteria checklists supplied, however, within the application review procedure rather than the personnel requirements procedure) supplied linking to the requirements of this particular clause requirement(s). This document only refers to the evaluation of personnel and it is therefore questioned if this is the only available document. This procedure is to be reviewed during the on-site visit when it is possible to determine other related procedures and/or processes regarding personnel.<br>2. The particular new requirements have not been dealt with (in the one document supplied).<br>***Comments/actions on-site:***<br>*No work was done on this document.* |
| **7.2 Personnel involved in the certification activities** | |
| ***Extra reqmt*** | **Comments**<br>The unique requirements of this clause need to be determined by the on-site activities. Limited documents on personnel requirements information were included for the document review and those included are most probably not the only documents. The review of these aspects would be more effective once on-site. |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| 7.2.1<br>7.2.2<br>7.2.3<br>7.2.4<br>**note**<br>7.2.5<br>7.2.6<br>7.2.7<br>7.2.8<br>7.2.9<br>7.2.10<br>7.2.11<br>7.2.12 | No particular document given and no particular statements made.<br>Some references made about personnel in the certification process document, however, would need to be discussed during the on-site visit.<br>***Comments/actions on-site:***<br>*Various and lengthy discussions about the competency of personnel required for FSMS certification took place. Various recommendations were made, and the various types of discussions and recommendations are included in this document, the project report and action plan list.* |
| **7.3 Use of individual external auditors and external technical experts** | |
| - | No particular document given and no particular statements made.<br>***Comments/actions on-site:***<br>*An auditor or technical expert agreement was presented during the on-site visit. It would be required to review this document as especially the format and writing style may not be of a legal format.*<br>*Time did not permit the full evaluation and retyping of this document.* |
| **7.4 Personnel records** | |
| - | No particular document given and no particular statements made.<br>To be reviewed on-site.<br>***Comments/actions on-site:***<br>*No particular records for FSMS personnel exist. Auditor files for QMS auditors were available, however, not particularly evaluated as the FSMS records would need to be unique for food safety.* |
| **7.5 Outsourcing** | |
| 7.5.1<br>7.5.2<br>7.5.3<br>7.5.4 | **Comments**<br>Procedure for assessing competence of bodies providing outsourced services – OP/CD/1.6<br>1. It was not clear from this document what types of services may or will be outsourced. The process description seems in order, however, it would need to be assessed on-site to determine its feasibility and correctness of the contents regarding the type of service to be outsourced and its impact on FSMS certification.<br>***Comments/actions on-site:***<br>*No work was done on this document.* |
| **8 Information requirements** | |
| ***Extra reqmt*** | No document given and no particular statements made.<br>To be reviewed on-site. |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| **8.1 Publicly accessible information** | |
| 8.1.1 | **Comments** |
| 8.1.2 | Publicly accessible information of certified companies – OF/CD/1.39 |
| 8.1.3 | This was a form, however, it did not contain any information. This will have to be assessed on-site. |
| 8.1.4 | ***Comments/actions on-site:*** |
| | *A form was available, and the Quality Manager had an additional spreadsheet containing information. Food safety aspects can be included in these documents. Not much time was spent on this document as it was already 'approved' and no FSMS related information could be challenged.* |
| **8.2 Certification documents** | |
| 8.2.1 | No particular document given and no particular statements made. |
| 8.2.2 | To be reviewed on-site. |
| 8.2.3 | ***Comments/actions on-site:*** |
| | *See various comments in this report, project report and action plan.* |
| **8.3 Directory of certified clients** | |
| – | No particular document given and no particular statements made. |
| | To be reviewed on-site. |
| | ***Comments/actions on-site:*** |
| | *Was available for QMS. Would need to include FSMS clients as soon as they become available.* |
| **8.4 Reference to certification and use of marks** | |
| 8.4.1 | No particular document given and no particular statements made. |
| 8.4.2 | To be reviewed on-site. |
| 8.4.3 | ***Comments/actions on-site:*** |
| 8.4.4 | *Information was added to the certification agreement.* |
| **8.5 Confidentiality** | |
| 8.5.1 | A statement in terms of a policy was available in the Quality Manual. |
| 8.5.2 | No other particular document given and no other particular statements made. |
| 8.5.3 | To be reviewed on-site. |
| 8.5.4 | ***Comments/actions on-site:*** |
| 8.5.5 | *Information was added to the certification agreement. No work was done on the policy statement.* |
| 8.5.6 | |
| 8.5.7 | |
| **8.6 Information exchange between a CB and its clients** | |
| 8.6.1 | No particular document given and no particular statements made. |
| 8.6.2 | To be reviewed on-site. |
| 8.6.3 | ***Comments/actions on-site:*** |
| | *See various comments and notes in this report, project report and action plan.* |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| **9 Process requirements** | |
| **9.1 General requirements** | |
| ***Extra reqmt*** | **Comments**<br>The specific requirements of 9.1.2 and 9.1.4 under general requirements for the surveillance audit procedure – OP/CD/2.3 had not been dealt with.<br>**Recommendations**<br>Need to review this procedure in order to reflect the specific requirements stated by ISO/TS 22003. |
| **9.1.1.1**<br>**9.1.1.2**<br>**9.1.1.3** | These are new requirements, in general they should be operational owing to the process being normal practice in a CB and also owing to the accreditation status.<br>No particular document given and no particular statements made.<br>To be reviewed on-site. |
| **9.1.2.1**<br>**9.1.2.2.1**<br>**9.1.2.2.2**<br>**9.1.2.2.3**<br>**9.1.2.2.4**<br>**9.1.2.3** | **Comments**<br>Audit plan – OF/CD/2.17 and OF/CD/2.19<br>The audit plan(s) would need to reflect the audit objectives.<br>The stage 1 audit plan may need to also include reference to verification of externally developed control measures.<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments.<br>**Recommendations**<br>The stage 1 audit plan presented reflects the requirements of the standard. The way that the plan is drafted currently will make it very difficult to plan aspects in the various departments that need to be verified during the audit. It is recommended that the planning process methodology be reviewed during the on-site visit and in consultation with ECAE staff in order to demonstrate the difficulties that will occur by making use of the current planning method.<br>The FSMS ISO 22000 audit plan gives the options to be used as initial audit or surveillance audit or recertification audit, and reflects the clauses of ISO 22000 as the auditing subject. It is not recommended to have one template for the various types of audits that need to be conducted as the auditing scope, objectives, and various other aspects may be different. It is also not recommended to plan an audit in the sequence of the requirements of the standard as the actual application of the standard would not be in that sequence. The audit plan should rather reflect the application of the various requirements of the standard in the various departments or areas to be audited. It is recommended that the planning process methodology be reviewed during the on-site visit and in consultation with ECAE staff in order to demonstrate the difficulties that will occur by making use of the current planning method. |
| **9.1.3.1**<br>**9.1.3.2**<br>**9.1.3.3**<br>**9.1.3.4**<br>**9.1.3.5** | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| **9.1.4.1**<br>**9.1.4.2** | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| | requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| 9.1.5 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| 9.1.6 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| 9.1.7 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| 9.1.8 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| 9.1.9.1 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| 9.1.9.2 | **Comments**<br>Opening meeting – OF/CD/1.49<br>The majority of the requirements of the standard had been dealt with.<br>No reference was made to the use of an attendance register.<br>May need to include:<br>1. conditions under which the audit may be terminated;<br>2. confirmation that the audit team leader and members are responsible for the audit, its control, and execution in accordance with the audit plan;<br>3. confirmation of the language (not sure if this would be required); and<br>4. confirmation of the status of findings from the previous audit (when applicable).<br>**Recommendations**<br>Not clear if this is the procedure how to conduct the opening meeting.<br>If it is, it may need to include the purpose and basic requirements for conducting such a meeting.<br>If this is to be the working document, it is recommended that it be converted into a working format (actual form to be ticked) rather than a procedure format so that it can also aid in the record collection of the audit. |
| 9.1.9.3.1 | No particular document given and no particular statements made. |
| 9.1.9.3.2 | To be reviewed on-site. |
| 9.1.9.3.3 | |

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| 9.1.9.4.1 | No particular document given and no particular statements made.<br>To be reviewed on-site. |
| 9.1.9.4.2 | No particular document given and no particular statements made.<br>To be reviewed on-site. |
| 9.1.9.5.1 | **Comments**<br>ISO 22000:2005 audit checklist – OF/CD/2.14<br>Clause 8.5.2 was not included in the checklist.<br>The checklist referred to preventive action. This is not a requirement of ISO 22000.<br>The normal practice for establishing a checklist would be to change the requirements of the standard, especially those of the 'shall' requirements, into a question so that the auditor is prompted to ask the auditee for the presentation of evidence based on the 'shall' requirement and therefore in a question format. This checklist has not been written in a question format. It reflects (in column one) a summary of the requirements of the standard and then (in column two) list an expected list of documents to be reviewed.<br>The method used to establish this checklist will not aid the auditor in asking focused, appropriate and relevant questions to the auditee. By making use of the listed documents to review, the auditor will receive an 'expected outcome' rather than be doing an objective evaluation of evidence supplied by the auditee. The current listed documents were not regarded as correct in terms of the possible required documents per clause of the standard. This may be owing to a lack of practical application of food safety audits and therefore the list of documents to be reviewed may lead or even dictate to the auditor to only ask for those types of documented evidence when the auditee may have made use of other methods or documents. This would impact the objectivity of the auditor in the evaluation of evidence. The dictation of expected audit results may be worse when external auditors are used as the understanding of the checklist may not be as clear as expected owing to difficulties in communication about audit methodologies with such auditors.<br>It is therefore not recommended that the current method of establishing be used as a checklist as the questioning of the auditor may not effectively be prompted and the documents review column may even be perceived as a consulting method.<br>**Recommendations**<br>Re-establish the audit checklist and base the first column on a question format.<br>By using the established checklist, list the expected documents in the list through a communication or training session and build expected data in a training session rather than in a checklist used during an audit. This 'completed checklist' may then be used as a 'calibration' tool for auditors during calibration or training sessions. |
| 9.1.9.5.2 | No particular document given and no particular statements made. |
| 9.1.9.6.1 | To be reviewed on-site. |
| 9.1.9.6.2 | ***Comments/actions on-site:*** |
| 9.1.9.6.3 | *A document for the classification of nonconformities was presented during the on-site visit. It was, however, revised and retyped in order to provide for the relevant variances in the identification of findings (conformance or non-conformance or opportunities for improvement, etc.) rather than just non-conformances.* |
| 9.1.9.6.4 | |
| 9.1.9.7 | |
| 9.1.9.8.1 | **Comments** |
| 9.1.9.8.2 | Closing meeting – OF/CD/1.49 |
| 9.1.9.8.3 | The majority of the requirements of the standard had been dealt with.<br>No references made to the use of an attendance register.<br>May need to include: |

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| | 1. CB post audit activities;<br>2. information on complaints and appeals;<br>3. questions from the audit client;<br>4. final audit conclusions (linking with audit objectives, scope, criteria as from opening meeting). May need to refer to recommendations of certification;<br>5. advice that the audit was based on a sample, thus have an element of uncertainty;<br>6. repetition of the grading of non-conformances;<br>7. the CB process for handling the non-conformances and any consequences relating to the certification.<br>**Recommendations**<br>Not clear if this is the procedure how to conduct the closing meeting.<br>If it is, it may need to include the purpose and basic requirements for conducting such a meeting.<br>If this is to be the working document, it is recommended that it be converted into a working format (actual form to be ticked) rather than a procedure format so that it can also aid in the record collection of the audit. |
| 9.1.10.1 | **Comments** |
| 9.1.10.2 | Audit report – OF/CD/2.18<br>Audit report for stage 1 dealt with the majority of the requirements of the standard.<br>The following may need to be added:<br>1. On the front page – identification of the CB, audit objectives, audit scope (the organization identification, functional units (site) and processes); the contact person may need to reflect it as being the 'Management Rep or Food Safety Team Leader' and then the other audit team members or accompanying members also need to be listed.<br>2. The need to also establish if externally developed combination of control measures had been implemented – thus determine if those are suitable to the organization and in compliance with ISO 22000<br>3. The need to list or record parts of the FSMS audited in stage 1 that were determined to be fully implemented, effective, and in conformity with the standard as these aspects may not need to be re-audited during stage 2 (then this information needs to be transferred to the stage 2 report as well).<br>4. The evaluation of the client's site and location needs to be recorded and determined if it was regarded as adequate for the handling of food and determined adequate in preparation for the stage 2 audit.<br>5. A note on recording of the identification of unresolved issues occurred during the audit.<br>An example of a stage 1 report was reviewed. It was not clear if there are report 'templates' for the other audits, i.e. stage 2, surveillance, recertification, special audits and/or suspension, withdrawal, etc.<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments.<br>**Recommendations**<br>References made to 'Quality Manual' or 'quality documentation' may need to be changed to reflect 'Food safety' rather than quality.<br>Try to have one aspect in one column of working documents as it makes it easier for the |

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| | user to collect and record information and easier for the reviewer to see if a certain aspect has not been dealt with. For example, 1.6 of the stage 1 report refers to both internal audits and management review. Also point 2 as it refers to audit findings and recommendations.<br>May need to add a note to point 4 – date for stage 2 – to indicate the maximum requirements of six months between stages 1 and 2. And also to indicate that the results of stage 1 may lead to the postponement or cancellation of the stage 2 audit. |
| **9.1.11** | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| **9.1.12** | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| **9.1.13** | **Comments**<br>Surveillance audit procedure – OP/CD/2.3 and Recertification audit procedure – OP/CD/2.4 These procedures did not include the detailed requirements of this paragraph and may not reflect the current detailed actual practice being carried out for this requirement. See paragraphs 9.3 and 4 of this report for further comments. |
| **9.1.14**<br>**9.1.15** | **Comments**<br>A certification decision committee do exist, however, this specific requirement has not been reiterated in the documentation supplied. It may need to be included in a particular document describing the activities of this committee. |
| **9.2 Initial audit and certification** | |
| 9.2.1 | **Comments**<br>Application – OF/CD/2.1<br>Most of the requirements of the standard had been included in the application form.<br>The following may need to be added and/or clarified:<br>A Company details<br>1. It is not clear from whom the telephone, fax and email need to reflect information since the CEO or MD and Man Rep are listed further down on the form.<br>2. It is not clear why the financial status of the organization needs to be reflected.<br>3. The address details of the main office do not include the name of a contact person.<br>4. The blocks for the name of the CEO or MD also indicate 'position', thus the position is repeated.<br>5. It is not clear from the blocks for the name of the CEO or MD if it needs to be of the applicant or main organization or sites.<br>6. The blocks for the details of the Man Rep do not include space for his/her contact details such as telephone or email.<br>7. The words 'relevant' legal obligations may need to be explained with an example as it is not clear what is actually required.<br>8. The blocks requiring information on 'several premises' may also need to indicate if there are seasonal requirements for food or food materials.<br>9. The same blocks (several premises), may also include questions if certification is |

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| | required per site and/or one certification for all sites.<br>10. The blocks on current registration still refer to the QSAE.<br>11. The language blocks may need to indicate the need for an interpreter.<br><br>B Certification standards<br>1. Rather write out the title of the standards in full as it seems more complete and will clear up any difficulty in understanding what to apply for.<br>C Business details<br>1. This paragraph may rather be referred to as 'Management system details' so as not to confuse information between A and C.<br>2. The block on the scope may need to be clarified as the scope of the business or scope for certification or scope of the management system. A simplified list of the food categories may also be added to help the applicant with the required details.<br>3. Point (i) needs to be simplified for the applicant as 'detailed' may not be understood by all readers. This point also needs to indicate that it is for FSMSs.<br>4. For ISO 9001, add questions regarding the statement on exclusions and its justification.<br>5. For ISO 22000, request information on the seasonal handling or growth or handling or processing of foods or food materials.<br>6. Include questions on how long the applicant's management system has been in full operation and/or comments on its status at the time of application.<br>7. Include questions on documents or processes regarding their completeness and/or comments on the progress made and/or documents or processes still to be established or completed.<br>8. Include questions on the number of internal audits conducted and/or comments on their status.<br>9. Include questions on the number of management reviews conducted and/or comments on their status.<br>10. Point (iii) may need to reflect customers and not only the 'main' customers.<br>11. Point (iv) may need to define what is meant with 'technical' resources as it may not be understood by the applicant.<br>12. Point (vi) may need to be extended to establish if the consultant or external expert established or implemented or audited the applicant's management system. For FSMS it needs to be established if the applicant made use of externally developed control measures and/or its combinations.<br>13. Point (vii) may rather refer to stage 1 instead of 'first assessment'. The applicant needs to become familiar with the terms used.<br>14. Point (ix) may rather be put into a statement of correctness whereby the applicant can sign.<br>15. May need to add a question relating to the whether the applicant has been informed of the requirements of certification.<br>D Disposition of staff<br>1. The word 'disposition' may not be understood by the applicant.<br>2. The first blocks require information on full-time employees and then request information on both permanent and temporary staff.<br>3. The number of employees per shift may also need to be included per site if there are more than one to be included in the certification.<br>4. Note 1 – it is not clear what is meant by 'licence' referred to in the paragraph. It |

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| | also refers to the 'QSAE'.<br>5. Note 2 – refers to a 'quality manual'. May need to add the food safety or environmental manual options too. Not sure why the manual must be sent to the ECAE as stage 1 for FSMS needs to be conducted on site.<br><br>**Recommendations**<br>In general, the document is difficult to read and to follow and it is recommended that the document be reorganized in terms of format and flow of questions. This will not only assist the applicant, but will also assist the review committee in ensuring all information has been collected to make a review decision. |
| ***Extra reqmt*** | **Comments**<br>The extra requirement had been included in the application form. |
| 9.2.2.1<br>**9.2.2.2**<br>9.2.2.3<br>9.2.2.4<br>9.2.2.5 | **Comments**<br>Application review – OF/CD/2.1 (form)<br>The majority of the requirements of the standard had been included into the application review part of the form.<br>The following may need to be added and/or clarified:<br>E For the use of CB only<br>1. At point 1 and the last question of page 10, impartiality is repeated. May need to rephrase the question so that it only appears once.<br>2. The second question may need to be clear in what the 'difference in understanding' may be about.<br>3. For this paragraph of the form, add space to specify or justify why answers to questions are 'no', as this will determine the plan of action for the CB to deal with the issues and/or determine the information to be communicated back to the applicant, especially if the application is declined.<br>4. The question on the CB's ability to conduct the certification may need to refer to a division rather than the CB OR replace it with ECAE instead of CB as it reflects direct information from the standard rather than it being used in a custom-made manner for the CB. This specific question may further be supported by the criteria or collective review of criteria on the form in order to make the decision.<br>5. May need to add a question if the applicant has been provided with information about the requirements of the certification process and then maybe link it with question 2 if there is any misunderstanding or difference in understanding.<br>6. On page 11, the question refers to whether stage 1 and stage 2 can be conducted at the same time. This option may be seen as being in conflict with the requirements of the standard as the objective of stage 1 is to plan for stage 2 and the nonconformities raised during stage 1 may need to be corrected and effectively implemented in order to move to stage 2. The practicality and implications of this question may need to be reviewed.<br>7. Point 3.1 refers to E-A codes and economic sector. Not sure if this is the NACE (the European industry standard classification system for classifying business activities) codes being referred to and may need to add the specific food categories to include ISO/TS 22003 requirements.<br>8. Points 3.2 and 3.3 may need to include the type of competence required as well as reference made to the proposed team members or committee members that will be appointed to the specific applicant's certification process.<br>9. Add a statement if the certification process can proceed. Both yes and no may need to be justified. If no, especially, the applicant must be informed about such a decision and the form (or any other document) needs to reflect that |

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| | communication with the applicant took place.<br>10. Referenced documents not included for the review – Certification agreement – OF/CD/1.33, Customer offer/order letter – OF/CD/2.4, Auditors competence criteria checklist – OF/CD/1.15, Lead auditor/auditor/technical expert contact agreement – OF/CD/2.9<br>**Recommendations**<br>In general, the document is difficult to read and to follow and it is recommended that the document be reorganized in terms of format and flow of questions. This will not only assist the applicant but will also assist the review committee in ensuring all information has been collected to make a review decision.<br>**Comments**<br>Application review – OP/CD/2.1 (procedure)<br>The majority of the requirements of the standard had been included into the procedure.<br>The following may need to be added and/or clarified:<br>1. The purpose of the document does not clearly reflect the intention of the document, but rather gives a general statement of pre-inspection or audit process for product and management system certification. No mention is made about the auditor or expert contracting as reflected by the title.<br>2. Paragraph 4 only indicates the quality manager to be involved. This is questioned as the document further refers to other staff members participating in the process.<br>3. It is not clear from the procedure how it would be ensured that the review committee or staff complies with the required competencies for FSMS application reviews as stated by ISO/TS 22003.<br>4. Add the selection and appointment of the certification decision committee or staff relating to the application reviewed.<br>5. Paragraph 8 – records. The audit plan and audit record time were not referred to in the contents of the procedure. A letter op appointment for the team of auditors is referenced, however, the contents of the procedure refer to a contract. The record of the client accepting or rejecting the audit team was not included.<br>6. Paragraph 9 – related documents. The auditor's competence criteria checklist would rather seem to be a record, especially once it has been completed. This was not listed as a record. The ISO 9001 audit checklist and audit planning form were not referenced in the contents of the procedure.<br>**Recommendations**<br>The document in its contents refers to the 'auditee' where it would be more accurate to refer to the 'audit client' as stipulated by ISO 19011.<br>The document makes reference to the 'certification body' where it would be more feasible to make reference to the 'ECAE'.<br>The combined information between paragraphs 8 (records) and 9 (related documents) indicates to reference all required documents, however, as individual paragraphs they lack the correct document references. It is recommended that these two paragraphs be combined under one heading or to ensure that the paragraphs accurately reference the required documentation or to remove the related documents paragraph as the reference documents are described in the contents of the procedure. |
| ***Extra reqmt*** | It is not clear from the initial audit procedure if the particular requirements of this clause have been dealt with. |
| 9.2.3.1.1 | **Comments** |
| 9.2.3.1.2 | Initial audit procedure – OP/CD/2.2 |
| 9.2.3.1.3 | The majority of the information included in the procedure seems to follow the process of a |

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| 9.2.3.2 | typical stage 1 and stage 2 audit.<br>The following may need to be added and/or clarified:<br>1. The reference documents paragraph makes reference to ISO 9001 and ISO 19011. This would rather need to reflect ISO/IEC 17021 and ISO/TS 22003.<br>2. It is not clear from this procedure if the actual requirements for FSMS certification had been dealt with as the majority of the information refers to ISO 9001 or quality management system documents and/or activities. The procedure would rather be reviewed in full during the on-site visit as it required further discussions based on FSMS specific requirements.<br>3. FSMS stage 1 audits are to be on-site. This procedure does not reflect this requirement.<br>4. The level of the responsible personnel carrying out particular tasks seems to be of a director's level rather of a level required for basic management. This would need to be discussed during the on-site visit as the functionality of such a level is questioned.<br>5. The information required for the certification committee for their decision had not been made clear by this procedure.<br>6. The new requirements of ISO/IEC 17021 have also not yet been incorporated and/or referenced in this procedure (see lists in the surveillance and recertification procedure comments paragraph).<br>7. Reference made to the definition and grading of nonconformities – OP/CD/1.47. This document was not included for the review.<br>**Recommendation**<br>This procedure and the process may need to be discussed and evaluated against the procedure during the on-site visit as it is not clear if it has been reviewed to include the specific requirements for food safety. |
| 9.2.4 | This aspect has not been stated clearly in the initial audit procedure. |
| 9.2.5.1<br>9.2.5.2 | **Comments**<br>Certification committee working procedure – OP/CD/1.10<br>FSMS, Certification committee major responsibilities – MR/CD/1.5<br>The following comments may need to be discussed:<br>1. The information contained in the MR document is also included in the procedure document. It is not recommended to document a subject in two or more documents as it makes the control of documents and therefore the information difficult. There is a possibility that one document will be updated, but the other one will not.<br>2. The MR document still refers to the QSAE.<br>3. FSMS is added to the MR document, however, it can be a document generic for any certification scheme. The document paragraphs can be identified as particular for QMS or FSMS requirements. It is implied by the 'FSMS' part of the title of the document that a similar document for QMS may exist. This is once again not recommended as this committee has a general function and if needed the unique requirements can be identified in individual paragraphs.<br>4. The responsibilities listed in the MR document seem to be the minimum. This would need to be verified during the on-site visit.<br>5. It is not clear from the MR document, in the first paragraph, if the specific requirements for food safety have been taken into account. The competencies of the listed members would have to be assessed during the on-site visit.<br>6. The competency requirements of the committed had been added to the MR document. It is questioned whether this is the appropriate place to state |

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| | competencies.<br>7. It is not clear how the impartiality requirements stated in the MR document will be realized.<br>8. The procedure document makes reference to both the product and management system certification schemes. This may not be advisable as these two aspects are different and may need to be managed separately.<br>9. The words 'audit' or 'auditors' and 'assessment or 'assessors' are used inconsistently. The word 'audit' would be more appropriate as this is the terminology used by the standards.<br>10. The procedure makes reference to the committee evaluating the audit report. This is questioned as there are various other required aspects to be considered during the certification decisions process.<br>11. It is not clear if there is a particular record created by this committed as evidence of the audit data evaluated and the decision made. The records paragraph refers to records by example instead of listing the actual required records.<br>12. Referenced documents not included in the review – certification committee documents registration logbook – OF/CD/1.26, list of documents to which internal and external parties have access – OF/CD/2.10.<br>**Recommendations**<br>It is recommended that separation of product and management system certification documentation be considered. These two services may be similar, but the implementation requirement documents may in certain aspects be different. The integration of these two aspects may make the management of documentation very cumbersome and difficult to handle. |
| **9.3 Surveillance activities** | |
| 9.3.1.1<br>9.3.1.2<br>9.3.2.1<br>9.3.2.2<br>9.3.3 | **Comments**<br><u>Surveillance audit procedure</u> – OP/CD/2.3<br>The majority of the minimum requirements of the standard were dealt with by this procedure.<br>The following may need to be added and/or clarified:<br>1. No reference is made to the communication of the audit plan and audit team members to the audit client's and his/her acceptance or rejection of the planned audit activities and/or team members.<br>2. Point 4 of the description of process steps makes reference to documents, however, their titles are not included and the related documents paragraph did not include one of the documents referred to. Thus, references used in the contents of the document were not always clear.<br>3. Reference in point 4 of the description of process steps makes reference to the use of an ISO 9001 audit checklist for the competence of audit team members. This may need to be evaluated further during the on-site visit to establish its applicability within the contents of this paragraph.<br>4. No reference is made to the option or consideration of multisite auditing and/or reference to a document specifying such criteria.<br>5. No reference made to the determination of audit time.<br>6. Point 7 of description of process steps makes reference to 'no process description required', however, it may need to state what is communicated and to whom communication is sent – also referenced in the process flow as communication.<br>7. Point 8 of the description of process steps refers to the certification committee. It is not clear why surveillance audits are to be assessed by this committee. This aspect may need to be discussed during the on-site visit. |

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| | 8. No reference is made to the monitoring of non-conformances raised during an audit in relation to the required correction and/or corrective action required by the audit client.<br>9. Inconsistent inclusion of information is given between paragraphs 8 and 9 regarding the required records to be kept and the related referenced documents. For example, OF/CD/1.45 is not included in paragraph 9. Non-conformance reports and communication to and from the audit client and the ECAE are not listed as required records. 'Results of corrective actions' are listed as a record under paragraph 8, however, do not appear in the body of the document.<br>10. Point 9 of the description of process steps refers to the criteria for certification suspension, reduction or withdrawal, however, no reference to such procedures was made under paragraph 9 – related documents.<br>11. The details of 9.1.2 and 9.1.4 – general requirements of ISO/TS 22003, had not been clearly described in this procedure.<br>12. Referenced documents not included for the review – ISO 9001 audit checklist - OF/CD/1.15, No title given – OF/CD/1.45, Definition and grading of non-conformances – OF/CD/1.47.<br>**Recommendations**<br>Some paragraphs in the procedure reflected the actual wording from the standard. This may be considered adequate in terms of a document review, however, it may need to be expanded on owing to actual practice where a more descriptive paragraph on the actual methodologies of activities is required. This may only be established during the on-site visit.<br>Point 10 of the description of process steps of the procedure refers to paragraphs of ISO/IEC 17025. This is not recommended as the user of the document may not have a copy of such a standard and/or may interpret the referenced requirements in his/her own way. This may lead to an inconsistent application of working methodologies between the document users.<br>In general, the details on the actual carrying out of the audit from the planning phase up to completion of the audit reflected limited details. Such details are now also required by the updated version of ISO/IEC 17021 and it is therefore recommended to revise and update this procedure to reflect a more detailed description of the actual practice of the processes involved during surveillance audits. The details referred to are dealt with in the following clauses of ISO/IEC 17021 (2011):<br>• 9.1.2 – Audit plan<br>• 9.1.3 – Audit team selection and assignments<br>• 9.1.4 – Determining audit time<br>• 9.1.5 – Multi-site sampling<br>• 9.1.6 – Communication of audit team tasks<br>• 9.1.7 – Communication concerning audit team members<br>• 9.1.8 – Communication of audit plan<br>• 9.1.9 – Conducting on-site audits<br>• 9.1.10 – Audit report<br>• 9.1.11 – Cause analysis of nonconformities<br>• 9.1.12 – Effectiveness of corrections and corrective actions<br>• 9.1.13 - Additional audits |

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| **9.4 Recertification** | |
| 9.4.1.1<br>9.4.1.2<br>9.4.1.3<br>9.4.1.4<br>9.4.2.1<br>9.4.2.2<br>9.4.3 | **Comments**<br><br><u>Recertification audit procedure</u> – OP/CD/2.4<br><br>The majority of the minimum requirements of the standard were dealt with by this procedure.<br><br>The following may need to be added and/or clarified:<br><br>1. Points 3 and 6 of the description of process steps seem to describe similar information.<br><br>2. The decision-making information and/or criteria used by the committee may be limited in point 8 of the description of process steps. For example, the overall performance of the client's management system, previous surveillance audit reports, decisions on multi-sites and their specific criteria as well as the demonstrated commitment to maintain the effectiveness and improvement of the clients management system needs to be included in the evaluation or decision-making criteria. Reference is also made to the 'intended outputs' achieved. This may need to be clarified in terms of 'product output' or 'system output in achieving its policy and objectives'.<br><br>3. The records paragraph makes reference to the recertification audit schedule, however, it was not referenced in the contents of the procedure. No reference is made to the keeping of recertification decision and/or communication records.<br><br>4. Some documents listed in paragraph 9 – related documents were not referenced in the contents of the procedure, i.e. the ISO 9001 audit checklist, nonconformity report, corrective/preventive action plan, ISO 9001 audit plan and ISO 9001 audit report.<br><br>5. Referenced documents not included for the review – Auditor competence criteria checklist – OF/CD/1.15, Technical experts competence criteria checklist – OF/CD/1.40, Definition and grading of nonconformities – OF/CD/1.47.<br><br>**Recommendations**<br><br>Points 2 and 3 of the description of process steps of the procedure refer to paragraphs of ISO 19011. This is not recommended as the user of the document may not have a copy of such a standard and/or may interpret the referenced requirements in his/her own way. This may lead to inconsistent application of working methodologies between the document users.<br><br>The document in its contents refers to the 'auditee' where it would be more accurate to refer to the 'audit client' as stipulated by ISO 19011.<br><br>In general, the details on the actual carrying out of the recertification audit from the planning phase up to completion of the audit reflected limited details. Such details are now also required by the updated version of ISO/IEC 17021 and it is therefore recommended to revise and update this procedure to reflect a more detailed description of the actual practice of the processes involved during recertification audits. The details referred to are dealt with in the following clauses of ISO/IEC 17021 (2011):<br><br>• 9.1.2 – Audit plan<br>• 9.1.3 – Audit team selection and assignments<br>• 9.1.4 – Determining audit time<br>• 9.1.5 – Multi-site sampling<br>• 9.1.6 – Communication of audit team tasks<br>• 9.1.7 – Communication concerning audit team members<br>• 9.1.8 – Communication of audit plan<br>• 9.1.9 – Conducting on-site audits |

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| | • 9.1.10 – Audit report<br>• 9.1.11 – Cause analysis of nonconformities<br>• 9.1.12 – Effectiveness of corrections and corrective actions<br>• 9.1.13 – Additional audits |
| **9.5 Special audits** | |
| 9.5.1 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3<br>The information in the procedure reflects the wording of the standard and therefore may seem to comply with the requirements of the standard, however, the actual activities, processes, decision-making criteria, etc. involved in carrying out this process may need to be described to ensure the effectiveness of the process once conducted.<br>**Recommendations**<br>The procedure would need to be updated to reflect the actual details of the processes required to carry out the activity. |
| 9.5.2 | **Comments**<br>Surveillance audit procedure – OP/CD/2.3<br>The information in the procedure reflects the wording of the standard and therefore may seem to comply with the requirements of the standard, however, the actual activities, processes, decision-making criteria, etc. involved in carrying out this process may need to be described in order to ensure the effectiveness of the process once conducted.<br>**Recommendations**<br>The procedure would need to be updated to reflect the actual details of the processes required to carry out the activity. |
| **9.6 Suspending, withdrawing or reducing the scope of certification** | |
| 9.6.1<br>9.6.2<br>9.6.3<br>9.6.4<br>9.6.5<br>9.6.6<br>9.6.7 | **Comments**<br>Criteria for certification suspension, withdrawal or scope reduction – OF/CD/1.14<br>1. This is referred to as a criteria document. It is, however, identified as being a form in terms of the identification number prefix. This may need to be clarified.<br>2. The standard required a policy and procedure to be available regarding this particular requirement. This document does not reflect the format of a procedure and/or policy and it is therefore not clear if any other documents regarding these requirements exist.<br>3. It is not clear from this document 'how' including the specific responsibilities of the 'how' will be conducted once a certification needs to be suspended, withdrawal or the scope reduced.<br>**Recommendations**<br>This document may need to be evaluated on-site as there may be other related procedures or processes. |
| **9.7 Appeals** | |
| 9.7.1<br>9.7.2<br>9.7.3<br>9.7.4<br>9.7.5<br>9.7.6 | **Comments**<br>Appeals on certification decisions handling procedure – OP/CD/1.12<br>The majority of the minimum requirements of the standard were dealt with by this procedure.<br>The following may need to be added and/or clarified:<br>1. Reference is made to the ISO 9000 series and ISO 2200 documents, although |

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| 9.7.7<br>9.7.8 | they do not play a role in the requirements of this procedure.<br>2. The purpose paragraph refers to the objective of handling of appeals to be of an improvement to the certification services aspect. This is questioned as the objective would rather be to effectively resolve the appeal and apply effective corrective action.<br>3. The process description refers to the appellant being able to forward an appeal to the committee for safeguarding impartiality. The process flow diagram does not reflect these actions and its related responsibilities.<br>4. The records paragraph makes reference to an appeals resolution report, however, it is not referenced in the body of the document and it is not clear if there should be a minimum type of information included in such a report.<br>5. The records paragraph required records to be kept for three years, however, the records procedure requires six years.<br>6. Referenced documents not included for the review – appeal application form – OF/CD/1.41, customer appeal/complaint registration logbook – OF/CD/1.8.<br>**Recommendations**<br>It is recommended that the process be reviewed during the on-site visit to ensure it is of a practical stance.<br>***Comments/actions on-site:***<br>*The document was not worked on during the on-site visit.* |
| **9.8 Complaints** | |
| 9.8.1<br>9.8.2<br>9.8.3<br>9.8.4<br>9.8.5<br>9.8.6<br>9.8.7<br>9.8.8<br>9.8.9<br>9.8.10 | Comments<br><u>Complaints and appeals handling procedure</u> – OP/CD/1.9<br>The majority of the minimum requirements of the standard were dealt with by this procedure.<br>The following may need to be added and/or clarified:<br>1. Reference is made to the ISO 9000 series and ISO 2200 documents, although they do not play a role in the requirements of this procedure.<br>2. The title and the body of this procedure include reference to both appeals and complaints. This needs to be clarified as an appeals procedure already exists.<br>3. Reference is made to the committee for safeguarding impartiality in the process description, however, is not included in the process flow.<br>4. The referenced form to be competed is in this document referred to as the complaints application form with number – OF/CD/1.41. The appeals procedure refers to the same form number but with the title being the appeals application form.<br>**Recommendations**<br>It is recommended that the process be reviewed during the on-site visit to ensure it is of a practical stance. Also, with the combination of the appeals and complaints concepts in this procedure, it will have to be determined on-site if there is a good understanding between the two aspects and also the handling of the two aspects.<br>***Comments/actions on-site:***<br>*The document was not worked on during the on-site visit.* |
| **9.9 Records of applicants and clients** | |
| 9.9.1<br>9.9.2<br>9.9.3 | No particular document given and no particular statements made.<br>To be reviewed on-site. |

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| 9.9.4 | |
| **10 Management system requirements for CBs** | |
| **10.1 Options** | |
| - | N/A |
| **10.2 Option 1** | |
| 10.2.1 | Option 1 was used for the establishment of the quality manual. |
| 10.2.2 | |
| 10.2.3 | |
| 10.2.4 | |
| **10.3 Option 2** | |
| 10.3.1 | Some of the information was supplied in the quality manual (it was not fully evaluated during the office document review as the document was received after this period and time did not permit for a full evaluation prior to the on-site visit). |
| 10.3.2 | ECAE Cert Quality Manual – M/CD/1.2<br>**Comments:**<br>The majority of the requirements of the standard were dealt with by this document.<br>The following may need to be added and/or clarified:<br>1. The document needs to be reviewed to reflect the 2011 requirements of the ISO/IEC 17021.<br>2. The reference documents paragraph includes reference to ISO 9001 (2008), which is not necessarily the document to be used for the establishment of the Quality Manual. Also, if ISO 9001 is referenced, there should be an equal reference to ISO 22000.<br>3. The reference documents paragraph does not include any reference to the use of the IAF mandatory documents.<br>4. Some paragraphs reflect information identified by bullet points and others by tick marks. The application of consistency of writing methods needs to be established as the current practice reflects unprofessionally in terms of the management of documents and their contents.<br>5. Paragraph 7 – General management system requirements, did not include and/or made reference to the establishment and documenting of the policy and objectives and it also did not include and/or made reference to the person that was nominated or appointed to be the management representative (later on under paragraph 7.2 Document management and control – reference, only in brackets, was made to the man rep).<br>6. The words ‘audits’ and ‘assessments’ were used throughout this document. Normal certification practice refers to ‘audits’ and not assessments and is used by the accreditation body. A decision on the use of the correct phrase to describe the actions of the CB will have to be made.<br>7. Some of the paragraphs in this manual did not always reflect the description of the title of the specific paragraph. For example, paragraph 7.1 Management Review. Very little of this paragraph actually reflects the activities around management review. Paragraph 7.2 Document management and control, seemed to describe the control of documents, but very little information was given on the control of records in relation to the description of controlled documents. Paragraph 7.3 Internal audit, includes aspects of continual improvement and the type of data to be reviewed for such a purpose.<br>8. The reference to actual procedures and the inclusion of their numbers as |

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| | references and therefore evidence of establishment of documents relating to the compliance with the ISO/IEC 17021 standard, was very limited. A quality manual normally reflects in its contents or in an addendum the documents established in support of the manual, the management system and therefore compliance with the management system standard.<br>9. In general, the writing of information in this document reflected that various paragraphs and/or sentences had been repeated. Some in the same paragraph and others in different paragraphs throughout the document. This does not only influence the reading of the document negatively but may lead to the ineffective control of information in the document should an aspect be updated or changed, it will be difficult to also correct the repeated sentences and/or paragraphs. That may lead to conflict of information.<br>10. Although the principles of certification are not an official requirement, the principles listed under paragraph 5 – Principles for certifying companies of the manual, however, only include the list. No further elaboration on how these principles will be achieved has been included in this paragraph. The inclusion of such information will support the commitment to compliance with the principles, especially during an accreditation assessment. The inclusion of the impartiality and confidentiality policy was the only reference to the possible explanation of these principles.<br>11. The strategy and leadership, vision, missions and policies contained in the manual were not updated as this is for the certification personnel and it is outside the structure of making such changes. Where possible, the English writing was improved without changing the contents or meaning of the statements.<br>**Recommendations:**<br>It is recommended that the quality manual be revised and structured to be more in line with the clause requirements of the standards. This would ensure that all aspects have been dealt with and will make it an easier document to work with during internal and accreditation audits. |
| 10.3.3 | **Comments**<br><u>Control of documents</u> – OP/CD/1.1<br>Most of the requirements of the standard were dealt with by this procedure.<br>The following may need to be added and/or clarified:<br>1. The actual format or contents requirements need to be specified.<br>2. Paragraph meanings need to be clarified as to the proposed contents required for a specific paragraph.<br>3. The process flow diagram figures used need to be specified.<br>4. A format for documents that needs not comply with procedural format needs to be specified, i.e. for policies, agreements, forms or working documents and criteria specifying documents.<br>5. The concept of external documents may need to be clarified as external documents had not been specified, however, the procedure does refer to external documents and various documents reviewed indicated by a number ‘2’ in the numbering identifying it as being ‘external’. This identification is not what is intended by the standard and the presumption was made that those documents identified with a ‘2’ have been indicated as working documents to be used outside (‘external’) to the ECAE.<br>In general, for the documents to be reviewed, the following was found:<br>1. Various documents did not reflect the contents or format structure reflected by the document control procedure. In some cases, paragraph 4 – Involved, paragraph 5 – Indicators, paragraph 6 – Supplements to the process steps, and paragraph 7 – General supplements, were either included or excluded. An overall inconsistency |

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| | of application of paragraphs was found in the documentation supplied for the review. This may be due to the lack of information contained in the document control procedure. i.e. not explaining the meaning of the paragraphs or not giving the required format and structure of documents<br>2. Reference documents not supplied for the review – Document creation, change request form – OF/CD/1.12, Document templates, Change history log – OF/CD/1.31.<br>3. In general, the process flow chart writing may need to be reviewed – place the number of the block in front of the wording instead of at the bottom of the wording. It will save some space and prevent the writer to use different font sizes. This will aid consistency of contents of documents.<br>4. May need to look at the standardization of format and typing of documents as they were generally found to be inconsistent.<br>5. It was not clear in the documents given if there is an overall 'audit process' document available describing how to or when to or who must use the various working documents during the audit process.<br>6. The combined information between paragraphs 8 (records) and 9 (related documents) of procedures reviewed in various occasions indicated the reference to all required documents described by that procedure, however, as individual paragraphs often lacked the accurate references of documents referred to by the procedure. It is recommended that these two paragraphs be combined under one heading and/or to ensure that the paragraphs accurately reference the required documentation.<br>7. The reference documents paragraph in procedures refers to documents, however, it does not necessarily link to the procedure and/or it is not clear why such documents are referenced. For example, management review procedure refers to ISO 9001 and ISO 22000, and although they also have requirements for management review, it would not be applicable to the management review requirements stipulated by ISO/IEC 17021. ISO/IEC 17021 is referenced, however, ISO/TS 22003 is not referenced.<br>8. No mention has been made to the referencing or use of the IAF mandatory documents.<br>9. In general, the indicator paragraph of procedures should be dealt with. If no such information exists and /or cannot be determined, it is recommended that the paragraph be removed from the document contents as it does not serve any purpose.<br>10. In general, all documents should be reviewed to ensure that the definitions and abbreviations applicable to a specific document are reflected in this particular paragraph. A pure general statement of the applicability of ISO 9000, ISO/IEC 17000, and ISO 19011 does not automatically cover the required explanations required by a document. If a general statement is made, documents should be reviewed against the referenced documents to make sure the relevant definitions are explained.<br>**Recommendations**<br>The contents format of documents may need to be simplified and/or described more clearly in order to assist the developers and users with documentation. This will prevent inconsistency in application of paragraphs and therefore prevent the unintended inclusion and/or exclusion of information in documents.<br>The following documents were identified as 'external', however, they need to be clarified in their number identification as they are seen to be internal ECAE documents:<br>• OF/CD/2.17 – FSMS initial stage 1 audit plan<br>• OF/CD/2.19 – FSMS ISO 22000 audit plan |

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| | • OF/CD/2.16 – Criteria for certifying a mulit-site organization under one certificate<br>• OF/CD/2.14 – ISO 22000 audit checklist<br>• OF/CD/2.5 – Nonconformity report<br>• OF/CD/2.18 – Audit report for stage 1 audit FSMS<br>• OF/CD/2.1 – Application for QMS/FSMS certification<br>• OP/CD/2.1 – Client's application review<br>• OP/CD/2.3 – Surveillance audit procedure<br>• OP/CD/2.4 – Recertification audit procedure.<br>Editorial and practical application comments and recommendations should be made during the site visit. |
| 10.3.4 | **Comments**<br>Records control procedure – OP/CD/1.2<br>The majority of the requirements of the standard were dealt with by this procedure.<br>The validity of the information contained in this procedure may need to be verified during the site visit and recommendations made if required.<br>In general the following can be commented on:<br>1. Point 6 (records) refers to 'all records' that are to be maintained for six years. The keeping of personnel records may need to be considered for a longer period.<br>2. May need to look at 'traceability' information of client files that would need to appear on all documents in all files. For example, a number + company name + department or team leader. This will assist in consistency of information and traceability of records of client files during the process of them being worked on and/or reviewed and/or if a file gets deteriorated, etc.<br>3. Compliance with the specific details of this procedure would need to be verified on-site, for example the particular identification requirements of client files. |
| 10.3.5.1 | **Comments** |
| 10.3.5.2 | Management review procedure – OP/CD/1.3 |
| 10.3.5.3 | Most of the requirements of the standard were dealt with by this procedure.<br>The following comments could be made and may need to be added, improved and/or clarified:<br>1. ISO 9001 and ISO 22000 are included in the reference documents paragraph and it is not clear why these documents are referenced.<br>2. Point 6.2 – Abbreviations, includes abbreviations which are not used in the body of the document. For example Exp – expert.<br>3. The process flow block 4 makes reference to a committee, however, it has not been clarified which committee is referred to and who is part of this committee.<br>4. Point 2 of the process steps description includes three members (DC, TL and QM). It is not clear if these are the only 'top management' members who will need to attend the meeting.<br>5. Point 3 of the process steps makes reference to ISO/IEC 17021 in terms of the items that need to be discussed during the management review meeting. It is recommended that the points of discussion in the procedure rather be included and/or be listed in a 'template' agenda.<br>6. Point 3 of the process steps makes reference to the frequency of management review and also includes an option stated as 'more frequently as appropriate'. The 'appropriate' frequency and/or meetings other than the scheduled meetings may need to be clarified. |

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| | 7. Point 4 of the process steps makes reference to the use of the corrective and preventive action procedure in order to deal with possible outcomes of the management review meeting. It is not recommended to 'fall back' on the system in terms of the use of a corrective action process to deal with meeting outcomes, but to rather identify action items in the minutes of the meeting and/or to establish an action item list including activities to be done, a responsible person and estimated target date. Outcomes of management review can rather been seen as system updates and/or system improvements rather than corrective actions.<br>8. Point 7 – Records, indicates that records for management review be kept for five years, however, the control of records procedure states that 'all' records be kept for six years.<br>9. The use of point 7 – Records, and point 8 – Related documents, was seen as in combination to capture the required records, but not in the records paragraph alone. It was not clear in the body of the document where, when and by whom the referenced related document under point 8 are to be used.<br>**Recommendations**<br>May need to attend to the agenda to also deal with food safety specific aspects.<br>The agenda was not included in the documents for review and could not be commented on.<br>***Comments/actions on-site:***<br>*The procedure was updated to include recommendations made, for example:*<br>• *Removing the ISO 9001 and ISO 22000 documents under the reference documents paragraph.*<br>• *Clarifying the committee members referenced under block 4 of the process flow. It was intended to be the management members and not in particular a committee.*<br>• *Removing the reference to the use of the corrective and preventive action procedure for the outcomes of the management review and replacing it with the minutes of the meeting to be actioned through an action list including responsibilities and target dates. It was further recommended that a person be nominated, for example, the Quality Manager, to manage the action items between the management review periods. A forum such as monthly management meetings may be used to carry out the monitoring of management review action items.*<br>• *Correcting the records paragraph to also reflect a six-year retention period as required by the records control procedure and to include the records generated in preparation of the management review process.*<br>*The recommendation to include the meeting discussion points into the procedure and/or making reference to a pre-set agenda template rather than making reference to the requirements of the standard in terms of management review inputs was not included as it was regarded as adequate and the accreditation body accepted the procedure and practice as is.*<br>*Minutes of a management review were not reviewed as food safety aspects had not yet been incorporated into the management review. Discussions and recommendations were made to ensure that QMS and FSMS certification scheme particular information, data and results are included in future management review meetings.* |
| 10.3.6.1 | **Comments** |
| 10.3.6.2 | Internal audit procedure – OP/CD/1.4 |
| 10.3.6.3 | The majority of the requirements of the standard were addressed by this procedure. |
| 10.3.6.4 | The following comments could be made and may need to be added, improved and/or clarified:<br>1. The referenced documents list includes ISO 9001 and ISO 22000, however, they |

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| | may be considered not applicable to the internal audit process. No reference was made to ISO/TS 22003.<br>2. The contents of the procedure do not include paragraph 4 – Involved, and paragraph 5 – Indicators.<br>3. The process flow chart did not under block 6 indicate responsibilities of the auditee as reflected in the process description.<br>4. In general, the process flow chart did not reflect the functions of corrective action and the audit follow-up activities as would normally be required for an audit process.<br>5. Point 2 of the process description indicates the DC to be responsible for the nomination of audit team members. It is recommended to have the QM responsible for this task as it is more relevant to this role.<br>6. The selection criteria of audit team members other than knowledge of certification, auditing and requirements of ISO/IEC 17021 have not been defined.<br>7. Point 2 of the process description does not make reference to ISO/TS 22003.<br>8. Point 4 of the process description only allows the development of an audit plan if the document review was found to be adequate. This needs to be clarified.<br>9. Point 5 of the process description requires the QM to approve audit plans. This may need to be discussed as the auditor should have the decision to generate and audit plan in accordance with his auditing method and/or working way.<br>10. Point 6 of the process description requires the auditee to agree in writing to the audit plan. This may need to be discussed as this process may complicate the feasibility of an audit.<br>11. Point 7 of the process description refers to 'clues suggesting non-conformities to be noted if they seem significant'. This may need to be discussed as it may not clearly reference the decision of a non-conformance to be based on audit evidence verses audit criteria as well as the decision on when a clue is significant or insignificant.<br>12. Point 7 of the process description allows the auditee to decide on the agreement on non-conformances. The noting of non-conformances is not clear in terms of where and/or how.<br>13. Point 8 of the process description refers to ISO 19011 for the contents of the audit report. It is recommended that the requirements or minimum requirements rather be stated or reference to the use of a template (that has been drawn up based on ISO 19011) be made.<br>14. Point 9 of the process description requires the DC to approve audit reports. It is recommended that the QM be responsible for such action.<br>15. Point 10 of the process description refers to a closing meeting, corrective actions and follow-ups, however, it is not reflected in the process flow chart. This is also referred to after the audit report, which is not in accordance with normal auditing practice.<br>16. Paragraph 6 – Records – refers to documents not referenced in the body of the procedure. Checklists referred to in the body of the procedure have not been listed in this paragraph. Minutes of opening and closing meetings are also referenced, however, they are not referenced in the body of the procedure.<br>17. Paragraph 7 – Related documents – refers to the ISO 9001 and ISO 22000 internal audit checklists. These documents may not be applicable to the internal audits described by this procedure. It should rather refer to ISO/IEC 17021 and ISO/TS 22003. |

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| | **Recommendations**<br>The management of the audit programme is the responsibility of the management representative (in this case the quality manager). Responsibilities for this programme were found to be shared between the DC and QM. It is therefore recommended that the necessary responsibilities be allocated to the QM as intended by the concept of the management of an audit programme as reflected by ISO 19011.<br>An example of an annual audit plan was not included in the documents for review. Its review and comments will be made during the site visit.<br>Auditing seems to be conducted against the clauses of the standard. Although this may be regarded as adequate to satisfy the requirements of the standard, its effectiveness in the objective evaluation of processes may be questioned. It is recommended to rather audit processes and then the related clauses of the standard pertaining to a particular process. This may include a combination of clauses rather than individual clauses of the standard.<br>Mention was not made on what types of aspects will need to be considered in order to determine the audit programme (annual audit plan) as well as any monitoring or review of the audit programme against a set objectives or targets.<br>**Comments**<br>FSMS Internal audit checklist – OF/CD/1.70<br>The following comments could be made:<br>1. This checklist has been based on the 2006 version of ISO/IEC 17021 and would therefore need to be reviewed to include the requirements of the 2011 version.<br>2. ISO/TS 22003 has not been included in the 'remarks' block contained on the first page.<br>3. Reference is made to 'assessors' rather than auditors which a more common word for certification auditors. Assessors are normally referred to by the accreditation body. The procedure also does not use the word 'assessors'. This may need to be clarified.<br>4. This document still refers to QSAE CERT.<br>**Recommendations**<br>The checklist seems to reflect the direct requirements of the ISO/IEC 17021 standard. It has not been drafted in a 'questioning' format as would be expected of a checklist and may also not been developed for the unique processes of the ECAE. The checklists will be beneficial in ensuring continued compliance with the ISO/IEC 17021 requirements, however, they may not support the evaluation of effectiveness of the various certification and systems processes employed by the ECAE. This type of checklist is good for a document review, but may need to be extended to reference specific procedures and/or process of the ECAE.<br>***Comments/actions on-site:***<br>*Audit planning in terms of an audit programme may not currently be conducted in accordance with the standard.*<br>*The concepts of an audit programme versus an audit process were explained and options for determining the audit programme were discussed and recommendations considered.*<br>*An example or template for an audit programme is to be established,*<br>*The use of one internal audit checklist for management system certification is to be established and would need to include all the requirements of ISO/IEC 17021 and ISO/TS 22003. A second internal audit checklist would need to be established for product certification.*<br>*The procedure was corrected with the following:*<br>• *Removed ISO 9001 and ISO 22000 from the reference documents paragraph.*<br>• *Added the NCR – non-conformance report to the abbreviations owing to it being used in the body of the document.*<br>• *Changed the responsibility of the DC for the selection of auditors to the QM as it is* |

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| | *more appropriate.* |
| 10.3.7 | **Comments** |
| 10.3.8 | Corrective and preventive action procedure – OP/CD/1.7<br>The majority of the requirements of the standard were dealt with by this procedure.<br>The following comments could be made and may need to be added, improved and/or clarified:<br>1. The referenced documents list includes ISO 9001 and ISO 22000, however, they may be considered not applicable to the internal audit process. No reference was made to ISO/TS 22003.<br>2. Paragraph 3 – Process owner. Reference is made to the DC to be the process owner. It is recommended that the responsibility be allocated to the QM as it is more appropriate to this role.<br>3. Reference is made in the body of the document to a record custodian (RC), however, it has not been included into the list of abbreviations.<br>4. Block 2 of the process flow chart indicates that root causes of actual and potential NC shall be determined. This is not in accordance with the standard as the root cause of potential NC is not determined, but rather the causes of the potential NC. This may need to be clarified.<br>5. The process flow chart does not include the 'correcting' step required for actual NC.<br>6. References are made to a record custodian in the process description paragraph, however, they were not reflected in the responsibility column of the process flow chart.<br>7. Point 8 of the process flow chart refers to 'verifying' rather than reviewing (in terms of the standard).<br>8. The need for action (step 3 of process flow chart) may be difficult to apply for the actual NC and potential NC as the actual NC is of a 'fixing' matter and the potential NC is of a 'preventing' matter. This may need to be clarified.<br>9. Point 1 of the process flow description mostly refers to non-conformances and not necessarily to aspects that will identify potential non-conformances. Reference is therefore not made to 'potential NC'.<br>10. Various steps of the process flow description make reference to the DC that is to assign staff, however, this function or responsibility has not been reflected in the responsibility column of the process flow chart.<br>11. Point 3 of the process steps description refers to the DC or TL or QM or RC to carry out a task. It is not clear who will decide on the actual responsible person or for what reason a person will be nominated. The responsibility is 'too loosely' identified.<br>12. The process flow chart includes two "no" answers at block 4, however, the process description steps do not clarify the two "no" options.<br>13. Paragraph 7 – Records – does not include the required record of rejections with reasons of non-conformance as described by point 5 of the process description.<br>14. It is not clear (by looking at paragraph – Records) if the 'non-conformities report form' needs to be used for potential nonconformities. The document does not refer to the use of an actual form for it.<br>15. 'RC' is used as an abbreviation in point 9 of the process step description, however, it is not reflected under abbreviations. It is also referred to in the process flow chart.<br>16. Paragraph 8 – Related documents – refers to a quality record registration form and service request form, however, it is not clear in the body of the document |

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| | where these documents are to be used.<br>17. No link has been made from this process (document) to the management review process (document) in terms of the trending of actual and potential non-conformances.<br>**Recommendations**<br>Corrective action and preventive action are two distinct processes. It is recommended that having each concept in its own procedure with its own forms be considered. Discussions on the concepts may need to take place in order to ensure a clear understanding of the two concepts and therefore the correct application thereof, especially if it is decided to have both concepts documented in one procedure and on one form.<br>Various activities have been allocated to the DC as a responsibility, where it may be more appropriate to allocate such responsibilities to the QM. This may need to be discussed.<br>***Comments/actions on-site:***<br>*The concept of corrective action and preventive action as two different processes with different intentions and uses was explained and discussed.*<br>*Currently the non-conformance report form used by auditors in the field is also used for corrective action internally. This is not a recommended practice. It was recommended that an internal corrective action form be developed.*<br>*Currently the corrective and preventive action procedure refers to the use of the NCR used by auditors in the field, however, the form does not allow for the recording of preventive action. Not all the paragraphs of this NCR form may be used for internal purposes and therefore also the recommendation to have an internal corrective form developed. Depending on the development of the corrective action form, preventive action steps may be included.* |
| | **Comments**<br>Customer satisfaction feedback collection and evaluation procedure – OP/CD/1.8<br>The following comments were made:<br>1. ISO 9001 and ISO 22000 are referenced as reference documents. ISO/IEC 17021 and ISO/TS 22003 have not been referenced.<br>2. Point 3 – Process owner. The DC has been nominated as process owner. It may be more appropriate to have the TL nominated as the overall process of 'customer satisfaction' remains with him.<br>3. The document number is indicated with a "1", which indicates internal use, however, the document is going to be completed by customers externally. This may need to be clarified.<br>4. Point 1 of the process steps description indicates the start of the process by receiving the pre-distributed survey and registration of the form. It is recommended that the process be started with sending out the form and then to continue with the registration process. It is not clear in the procedure who will be responsible for the 'pre-distribution' process.<br>5. Point 5 of the process steps description refers to the use of the corrective and preventive actions for dissatisfied customers. Corrective action may be applied, but preventive action is difficult to apply. This may need to be discussed. Then, point 8 – Records, refers to the nonconformity report. It is not clear if preventive actions are to be logged on this form.<br>6. The survey form will need to be reviewed during the site visit as it was not included in the documents for review.<br>7. Referenced document not included for the review – Customer satisfaction survey form – OF/CD/2.2.<br>**Recommendations**<br>The results of this process may need to be indicated that they will be trended and included |

| Clause | Document review<br>Comments and Recommendations |
|---|---|
| | in the management review meeting.<br><br>***Comments/actions on-site:***<br>*Currently the certification division is carrying out its own customer satisfaction surveys.*<br>*Also, currently, the customer services division is working on customer surveys and in future will have this as a central function. The survey forms are still being developed.*<br>*The procedure was also updated to reflect the process starting at the distribution of the survey documents rather than at the registration of the completed forms.*<br>*Establish for example an 'excel' spreadsheet containing a list of the customers with their identify numbers (i.e. the application number) and then the 'year' numbers in order to establish a selection matrix to indicate which customers over a period of years have been selected to participate in the surveys. The list will permanently be extended as customers are added. Colours may be used to indicate if customers have been suspended or extended or have a decreased scope, as their certification status may influence the selection of participating in the survey process.* |

**Annexure 4.1:** Study 1 action item list reflecting progress made with its implementation

| No | Action items | Progress |
|---|---|---|
| **A** | **Food safety management system certification scheme in general** | |
| 1 | Identify a specific nominated person (project champion) to take the project forward up to accreditation | No action taken |
| 2 | Nominate relevant participants of the project and determine biweekly project follow-up actions or meetings to pace the completion of the project | No action taken |
| 3 | Identify a more detailed action item list, time frame and detailed responsibilities for the completion of the project | No action taken |
| **B** | **Certification personnel** | |
| **B1** | **Application review committee members – Quality Manager – Certification** | |
| 1 | Identify an adequate pool of reviewers that comply with the education, food safety training and audit training criteria of ISO/TS 22003 | Action taken but to be completed |
| 2 | For those that do not have food safety training, schedule, ensure that they attend and verify such training | No action taken |
| 3 | For those that do not have audit training, schedule, ensure that they attend and verify such training | No action taken |
| 4 | For the pool identified, schedule the assessment of its competencies as stipulated by 7.2.2.4 of ISO/TS 22003 (2007) | No action taken |
| 5 | Establish corrective actions for those individuals who do not comply with the competency evaluation | No action taken |
| **B2** | **Certification decision committee – Team Leader – Certification** | |
| 6 | Identify an adequate internal pool of certification committee members that comply with the education, food safety training, audit training and work experience criteria of ISO/TS 22003 – within the food chain categories selected | No action taken |
| 7 | Identify an adequate external pool of certification committee members that comply with the education, food safety training, | No action taken |

| No | Action items | Progress |
|---|---|---|
| | audit training and work experience criteria of ISO/TS 22003 – within the food chain categories selected | |
| 8 | For those that do not have food safety training, schedule, ensure that they attend and verify such training | No action taken |
| 9 | For those that do not have audit training, schedule, ensure that they attend and verify such training | No action taken |
| 10 | For the pool identified, schedule the assessment of its competencies as stipulated by 7.2.3.2 of ISO/TS 22003 (2007) | No action taken |
| 11 | Establish corrective actions for those individuals who do not comply with the competency evaluation | No action taken |
| **B3** | **Impartiality committee – Director – Certification** | |
| 12 | No action needed | Action completed |
| **B4** | **Auditors – Team Leader – Certification** | |
| 13 | Evaluate current internal auditor pool against the education, food safety training, audit training, audit and work experience requirements of ISO/TS 22003 | No action taken |
| 14 | Advertise externally to the organization for auditors and technical experts | Action completed |
| 15 | Collect and review the information regarding external applicants in terms of education, food safety training, audit training, audit and work experience in accordance with ISO/TS 22003 | Action completed |
| 16 | List the external applicants against the selected food chain categories – also list other possible categories available | Action taken but to be completed |
| 17 | From the list of the internal pool and the external applicants, list all candidates that can be considered able to qualify as auditors and technical experts | Action taken but to be completed |
| 18 | Draw up a list of acceptable qualifications as well as acceptable institutions that do and will comply with the requirements of ISO/TS 22003 – use these criteria as internal criteria for the | No action taken |

| No | Action items | Progress |
|---|---|---|
| | acceptable education requirements | |
| 19 | From the final list of possible acceptable candidates, for those who do not have food safety training, schedule, ensure that they attend and verify such training | No action taken |
| 20 | From the final list of possible acceptable candidates, for those who do not have audit training, schedule, ensure that they attend and verify such training | No action taken |
| 21 | From the final list of possible acceptable candidates, for those who do not have audit experience, plan how the audit experience can be gained | No action taken |
| 22 | For those that do not have the immediate correct work experience, set up equivalent work experience such as retailing, inspection or enforcement. Determine how to meet the required work experience for those that are lacking | No action taken |
| 23 | For the final pool identified, schedule the assessment of its competencies as stipulated by 7.2.2.4 of ISO/TS 22003 (2007) | No action taken |
| 24 | Evaluate the list of registered auditors on the IRCA list to determine auditors and experts in Ethiopia and/or countries surrounding Ethiopia | No action taken |
| 25 | Communicate with the auditors on the IRCA list to determine their interest in auditing for the ECAE | No action taken |
| 26 | Identify a pool of experts (internal and/or external) in the selected food categories as these experts may be used for the purpose of auditing and certification decisions for each certification client. Estimate two nominations per category | No action taken |
| 27 | Communicate to the accreditation body the proposed auditor criteria and action plan to achieve compliance with ISO/TS 22003 | Action taken but to be completed |
| 28 | Determine the fees paid to external auditors in the certification market generally | Action completed |

| No | Action items | Progress |
|---|---|---|
| 29 | Benchmark the market fees against the current allowed fees to be paid for external auditors or experts | Action completed |
| 30 | If required, request for a fee revision for external auditors and experts to match the general fees in the industry | Action completed |
| 31 | Set up auditor or expert agreements for the selected external auditors or experts | No action taken |
| 32 | Ensure that the external auditor or expert agreement stipulates the required rules and requirements to protect the interest of the ECAE and the audit client | No action taken |
| 33 | Determine the time frame and methodologies for establishing 'calibration' sessions for auditors and experts | No action taken |
| 34 | Determine the contents of calibration sessions and/or the means to identify calibration session contents | No action taken |
| 35 | Develop a list of technical experts relating to the selected food chain categories | No action taken |
| 36 | Nominated audit teams for each food chain category would need to indicate overall compliance with the 'selection of audit teams' requirements of 7.2.6 of ISO/TS 22003 (2007). Predetermination of such teams are recommended | No action taken |
| **C** | **Certification scheme process and documentation** | |
| **C1** | **Certification schemes – Director – Planning and marketing** | |
| 1 | Determine the need for a particular food safety certification scheme | No action taken |
| **C2** | **Brochure – Director – Planning and marketing** | |
| 2 | Review the contents of the brochure to include the ECAE information | No action taken |
| 3 | Review the explained certification process in comparison with the new process included in the quality manual and the certification agreement during the site visit | No action taken |

| No | Action items | Progress |
|---|---|---|
| **C3** | **Certification certificate – Director – Planning and marketing** | |
| 4 | Investigate a suitable means of ensuring authenticity of the certificate | No action taken |
| **C4** | **Quality manual – Quality Manager – Certification** | |
| 5 | Review the quality manual as the contents in terms of layout have been changed, some paragraphs have been shortened to only give a basic description and reference to the particular procedures was included, however, not all the numbers may have been included | No action taken |
| **C5** | **Documentation in general – Quality Manager – Certification** | |
| 6 | Conduct a planning session for the overall structure development for documentation of the Certification Directorate to identify the generic documents, scheme specific technical documents, levels of documents within the directorate and departments and then the possible unique identification in terms of prefixes and numbering | No action taken |
| 7 | Conduct a general review or comparison with the FSMS documentation and the initial QMS documents to identify possible contradictions and especially where the new ISO/IEC 17021 requirements have been dealt with | No action taken |
| 8 | Ensure that all reviewed and updated documents reflect the document history as 'Reviewed and updated to reflect incorporation of the FSMS certification scheme' with authors and the effective date 'Sept 2011' | No action taken |
| 9 | Review all documents to ensure that the writing style is 'eurostile' and in font '12'. Add this information to the control of documents procedure as part of the writing requirements of a document | No action taken |
| 10 | Review all documents to ensure a standard use of the template for the contents of documents | No action taken |
| 11 | Decide on the identification of documents in terms of the prefixes to add or not to add a 'Q' for QMS-specific documentation and an | No action taken |

| No | Action items | Progress |
|---|---|---|
| | 'FS' for FSMS-specific documents | |
| 12 | Review all documents and replace ISO/IEC 17021:2006 with the 2011 version | No action taken |
| 13 | Review all documents and add ISO/TS 22003 as a reference document | No action taken |
| 14 | Review all documents and add the IAF mandatory references to where they are appropriate to the specific document | No action taken |
| 15 | Review all documents to ensure accurate reference is made to 'referenced documents' for each document and not to include ISO 9001 or ISO 22000 if it does not influence the use of the specific procedure | No action taken |
| 16 | Review all documents to ensure the use of the new reference to the certification documentation as management system certification' documentation | No action taken |
| 17 | Decide on the purpose, use and actual contents of paragraph 5, Indicators, of all procedures | Action taken but to be completed |
| 18 | Review all documents to ensure that the listed abbreviations under point 6 of the procedures are used in the body of the document and/or where abbreviations are used in the body of the document, that they are listed and explained under point 6 | No action taken |
| 19 | The approval block appearing in documents seems to move around depending on the user and/or during printing. The typing format of this block needs to change from a 'picture block' to a 'table block' as this will assist in keeping the approval block in one place during the use and printing of documents. All documents are to be reviewed and corrected to ensure the approvals block remains in the same place | No action taken |
| 20 | Review all procedures to remove bullet points in the process description paragraphs and replace them with 'enters' so that each new sentence starts at the left-hand side of the column | No action taken |

| No | Action items | Progress |
|---|---|---|
| 21 | Review the stand-alone vision, mission, quality policy, impartiality and confidentiality policy as those contained in the quality manual were minimally corrected in terms of the English | No action taken |
| 22 | Review documents against the comments and recommendations made in the document review list as some were dealt with and some may still need to be discussed and decided on | No action taken |
| **C6** | **Electronic versions of documents – Quality Manager – Certification** | |
| 23 | Identify the QM to be the 'master' holder of electronic versions of all documents | No action taken |
| 24 | Determine the documentation filing set-up in order to clearly identify general management systems, quality specific and food safety specific documents | No action taken |
| **C7** | **Management review – Quality Manager – Certification** | |
| 25 | Ensure that the next management review includes aspects of food safety certification activities | No action taken |
| **C8** | **Internal audits – Quality Manager – Certification** | |
| 26 | Establish an audit programme reflecting areas and processes of importance | No action taken |
| 27 | Update the internal audit checklist to reflect the requirements of ISO/IEC 17021 (2011) as well as the specific requirements of ISO/TS 22003 | No action taken |
| 28 | Establish and document internal audit selection criteria | No action taken |
| 29 | Establish an opening and closing meeting agenda and attendance registers | No action taken |
| 30 | Update the process flow diagram for the internal audits | No action taken |
| 31 | Ensure the availability of an internal auditor with a background in the food safety specific requirements, not only of ISO/TS 22003, but also the technicalities of the audit documentation for ISO 22000 | No action taken |

| No | Action items | Progress |
|---|---|---|
| **C9** | **Corrective and preventive action – Quality Manager – Certification** | |
| 32 | Split the corrective action process from the preventive action process | No action taken |
| 33 | Develop an internal corrective action form | No action taken |
| 34 | Develop an internal preventive action form | No action taken |
| 35 | Define corrective action and preventive action | No action taken |
| **C10** | **Customer surveys – Quality Manager – Certification** | |
| 36 | Establish for example an 'excel' spreadsheet containing a list of the customers with their identify numbers (i.e. the application number) and then the 'year' numbers to establish a selection matrix to indicate which customers over a period of years have been selected to participate in the surveys. The list will permanently be extended as customers are added. Colours may be used to indicate if customer have been suspended or extended or have a decreased scope, etc. as their certification status may influence the selection of participating in the survey process | No action taken |
| 37 | Correct the number for the survey form to be a '1' instead of a '2' | No action taken |
| **C11** | **Auditing processes – Quality Manager – Certification** | |
| 38 | Establish the opening and closing meeting attendance register<br>Add a column to the form to indicate a signature for the opening meeting and a signature for the closing meeting | No action taken |
| **D** | **Activities and interested parties related to certification** | |
| **D1** | **Standards and library – Head – Documentation and publications** | |
| 1 | Communicate with the standards body to generate and/or adopt standards for PRPs | Action completed |
| 2 | Make the required or selected standards available | No action taken |
| **D2** | **Training and consultation programmes for FSMS – Training and technical support directorate** | |

| No | Action items | Progress |
|---|---|---|
| 3 | Update the training materials to reflect ISO 22000 specific HACCP plan requirements versus only using Codex examples | No action taken |
| 4 | Plan to reattend a five-day training session to establish 'correctness' of information trained so that it is not in conflict with certification expectations | No action taken |
| 5 | Plan to have the training provider observe one or two FSMS certification audits to verify contents of the training material against the certification processes | No action taken |
| 6 | Plan for the participation of the consulting personnel to participate in training and auditing activities in order to ensure correct implementation recommendations to the certification client | No action taken |
| **D3** | **Ethiopian food handling market, marketing and new business development – Director – Planning and marketing** | |
| 7 | Investigate the need and readiness for ISO 22000 certification | No action taken |
| 8 | Investigate the food sectors currently available in Ethiopia | No action taken |
| 9 | Investigate the preferred food safety certification scheme | No action taken |
| 10 | Determine the number and types of food businesses – multinationals or local or SMMEs, etc. | No action taken |
| 11 | Establish the current certified status and willingness to move over | No action taken |
| 12 | Establish marketing strategy to move already certified clients to the ECAE | No action taken |
| 13 | Establish importance of accredited certification and/or no need to have accredited certification | No action taken |
| 14 | Develop marketing material and the marketing means for the FSMS certification scheme – add the relevant supporting services | No action taken |
| 15 | Develop a certification certificate for the FSMS certification scheme, and authenticate the certificate | No action taken |
| **D4** | **Laboratory services – Director – Laboratories** | |
| 16 | Determine the feasibility of microbiological and food chemical | No action taken |

| No | Action items | Progress |
|---|---|---|
| | testing | |
| 17 | Establish programmes to support the outcome of the survey | No action taken |
| 18 | Establish marketing material for the establishment of services to the food handling industry | No action taken |
| 19 | Revise the scope of accreditation to include the most requested tests of the food handling industry | No action taken |
| **D5** | **Human resources – Human Resources** | |
| 20 | No action required | Action completed |
| **D6** | **Financial and liability risk assessment – Finance and supplies Director** | |
| 21 | Assess the liability cover to include food safety liability | Action taken but to be completed |
| 22 | Determine the feasibility to be held accountable for the failure of a certified FSMS | No action taken |
| 23 | Conduct a risk assessment for liability based on food safety | No action taken |
| 24 | Conduct a financial risk assessment for the finances and sources of income of the FSMS certification scheme | No action taken |
| 25 | Establish a means to annually review the adequacy of the liability cover for the certification activities | No action taken |
| **D7** | **Legal services – Legal services** | |
| 26 | Review the certification agreement to ensure it is within Ethiopian written legal requirements | No action taken |
| 27 | Review the auditor or expert agreement to ensure it contains all the required information and is written within the Ethiopian legal requirements | No action taken |
| **D8** | **Ethiopian food legislation – Director General** | |
| 28 | Through the Director General initiate communication with the relevant role players for setting food legislation | No action taken |
| 29 | Nominate a certification person to be a contact person or participant with the role players to support the establishment of | No action taken |

| No | Action items | Progress |
|---|---|---|
| | food legislation. This may also include the setting up of compulsory standards | |
| 30 | Get copies of the relevant laws or draft laws | Action taken but to be completed |
| 31 | Evaluate their contents against the required PRP requirements of the ISO and GMP standard and determine feasibility for use and for auditing and implementation by the organization | No action taken |
| 32 | Decide on the 'interim' decision on recommending food legislation to a certification applicant as well as the conducting of a certification with a food handler with the interim plan | No action taken |
| 33 | Establish a process to have in place processes for when the food legislation is passed and becomes a legal requirement, how to communicate to certified clients, the period involved in allowing certified clients to incorporate legislation and the certification process thereof and/or suspension of certification when non-compliance with legislation is identified after the communicated date of implementation | No action taken |
| 34 | Interpret and understand the requirements and needs for food stipulated by the Federal Negarit Gazeta of 13 January 2010, Proclamation no 661/2009, and its support of other related food regulations and implications | No action taken |
| 35 | Draw up the necessary criteria documents and/or checklists to support the certification process | No action taken |
| 36 | Set up a training programme on the established legislation | No action taken |
| 37 | Ensure that the certification personnel attend the food legislation training programme | No action taken |